



September 21, 2001

Mr. Jim Tompkins, Product Manager (25)
Registration Division (7505C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460
via fax: 703-308-1825

Re: RO-NEET 6-E, SLN No. OR010023 - Notice of Intent to Disapprove

Dear Mr. Tompkins:

Since you are out of the office today, as well as the fact that the Agency has given us a limited amount of time to respond, I am submitting this letter to you by fax. If you recall, you recently sent a letter to Rose Kachadoorian at the Oregon Dept. of Agriculture, indicating that the Agency may disapprove RO-NEET SLN No. OR010023 for spinach unless we revise the label to include a 65-day preharvest interval. I was able to speak with Ms. Kachadoorian late yesterday to discuss the matter in detail, and after review of the data in the state's files, we feel that the data clearly indicate that residues are negligible at preharvest intervals well below 65 days, and in fact would support a preharvest interval of 50 days. I am taking this opportunity to attach one summary page of data; the report pages that support this summary are being sent to you via courier for delivery on Monday, September 24th.

RO-NEET and the SLN for spinach are important not only to Cedar, but to others as well - Ms. Kachadoorian and various groups have expressed the fact that they lack other options. We ask you to review the data at your earliest convenience and notify Cedar and the Oregon Dept. of Agriculture of any comments before further action is taken to disapprove the SLN.

If you have any questions or require additional information, I can be reached at 901-260-5423.

Sincerely,

A handwritten signature in cursive script that reads "Jeanine H. Betscher".

Jeanine H. Betscher
Director of Regulatory Affairs

cc: Rose Kachadoorian, OR Dept. of Agriculture

SUMMARY TABLE FOR CROP FIELD TRIALS

Residues of Cycloate on Spinach

(Acceptance Criteria 7, 8, 9)

<u>Location</u>	<u>Rate</u>	<u>Applic. Date</u>	<u>PHI</u>	<u>Commodity</u>	<u>Residue PPM</u>	<u>FSDS No.</u>	<u>MRID No.</u>
Freewater, OR	3.0	07/30/85	52	Leaf	<0.02	A-31423	
Walla Walla, WA	3.0	08/01/85	50	Leaf	<0.02	A-31420	
Lompoc, CA	5.0	07/25/85	42	Leaf	<0.02	A-29126	
Lompoc, CA	5.0	08/15/85	21	Leaf	<0.02	A-29125	
Lompoc, CA	5.0	08/01/85	35	Leaf	<0.02	A-29124	
Bordertown, NJ	3.0	03/26/85	49	Leaf	<0.02	A-06145	
Adelphia, NJ	4.0	04/21/65	55	Leaf	<0.02	A-1913	93484
Greenfield, CA	4.0	09/15/66	35	Leaf	<0.02	A-379	
		09/09/66	60	Leaf	<0.02		
			77	Leaf	<0.02		

Unwashed spinach leaves were analyzed.

Application rate in pounds active ingredient per acre.

All were ground applications, preplant incorporated, applied with 20 to 70 gallons of water per acre.

PHI = preharvest interval in days.

Control samples contained <0.02 ppm apparent residues.

Spinach samples from the above trials were stored at -20°C for 12 to 188 days prior to residue analysis. Storage stability studies show that cycloate is stable in alfalfa, almonds, apples, soil & wheat straw for a minimum of 3 years; in oranges, peppers, potatoes, soybeans & wheat grain for a minimum of 2 years; and in corn for 3 months when stored at -20°C. (Reference: Cycloate - storage stability: crops and soil, WRC 89-20, being submitted concurrently.)

Recoveries from control spinach samples spiked at 0.02 ppm and analyzed concurrently with the field treated samples were 75-130%. Analytical Methods used were RR-65-116 (MRID No. 115094) and RRC-85-56, being submitted concurrently.

~ 7/1/94

MEMORANDUM

SUBJECT: Cycloate. Case No. 2125. Magnitude of Residue Studies: Garden Beets, Sugar Beets, & Spinach, and Processing Study for Sugar Beets. MRID No. 42919701, -02, -03, and 42939701, -02. CBRS No. 12697 & 12830. DP Barcode: D195931 & D196714.

FROM: Leung Cheng, Chemist
Special Review Section II
Chemistry Branch II - Reregistration Support
Health Effects Division (7509C)

THROUGH: Andrew R. Rathman, Section Head
Chemistry Branch II - Reregistration Support
Health Effects Division (7509C)

TO: Kathryn Davis, CRM 52
Accelerated Reregistration Branch
Special Review/Reregistration Division (7508W)

Attached is a review of magnitude of residue studies on garden beets, sugar beets and spinach for cycloate submitted by the registrant for reregistration. This information was reviewed by Dynamac Corporation under the supervision of CBRS, HED. The data assessment has undergone secondary review in the branch and has been revised to reflect branch policies.

The registrant needs to submit frozen storage stability data for the three crop studies; these studies are underway. Also, the registrant needs to submit sugar beet residue data resulting from the application of the 10% G formulation and then propose tolerances for the combined residues of cycloate and its metabolites cis- and trans-3-hydroxycycloate, and cis- and trans-4-hydroxycycloate in/on sugar beet tops and roots to be consistent with the preharvest interval on the revised label.

The currently established tolerances, expressed as cycloate only, of 0.05 ppm in/on the roots and tops of garden beet are too low. The registrant must propose tolerances for the combined residues of cycloate and its metabolites cis- and trans-3-hydroxycycloate, and cis- and trans-4-hydroxycycloate in/on garden beet tops and roots at 1 and 0.5 ppm, respectively. The registrant should also revise their current label to propose a 65-day preharvest interval.

The registrant also must revise tolerances for the combined residues of cycloate and its metabolites cis- and trans-3-hydroxycycloate, and cis- and trans-4-hydroxycycloate in/on spinach

upward to 0.5 ppm. They also need to revise their label to include a 65-day preharvest interval.

The submitted sugar beet processing is acceptable. The data indicate that the combined residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) concentrated 3.5x in molasses processed from sugar beet that received a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation at 2x. No concentration of residues was observed in pulp and sugar processed from similarly treated sugar beet roots. The registrant must propose a feed additive tolerance for the combined residues of cycloate and its metabolites cis- and trans-3-hydroxycycloate, and cis- and trans-4-hydroxycycloate in molasses when all the reregistration requirements for the sugar beet roots and adequate supporting storage stability data have been submitted.

If you need additional information, please advise.

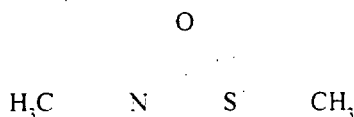
Attachment: Dynamac review of magnitude of residue studies

cc(with Attachment):Circ, RF, SF, List B File, Cheng, Dynamac

RDI:ARRathman:5/24/94:MMetzger:5/24/94:EZager:7/1/94

7509C:CBRS:LCheng:CM#2:RM8040D:5/23/94:7/1/94:03:a\CYCLOATE\MAGNRESI.DYN

CYCLOATE



Shaughnessy No. 041301; Case No. 2125

(CBRS No. 12697; DP Barcode D195931)

(CBRS No. 12830; DP Barcode D196714)

Task 4

REGISTRANT'S RESPONSE TO RESIDUE CHEMISTRY DATA REQUIREMENTS

BACKGROUND

The Cycloate Phase IV Reviews (S. Funk, 12/20/90) required field trial data depicting residues of cycloate and any regulated metabolites in/on the commodities of garden beets and spinach following application(s) of representative cycloate formulations in respective major crop-growing regions of the country according to the maximum registered use patterns. In addition, a sugar beet processing study was required to determine the potential for concentration of cycloate residues of concern in sugar beet processed fractions.

In response to the Cycloate Phase IV data requirements, Zeneca, Inc. (formerly ICI Americas, Inc.) has submitted data depicting the magnitude of the residues of cycloate, trans- and cis-3-hydroxycycloate (t-3HC and c-3HC), and trans- and cis-4-hydroxycycloate (t-4HC and c-4HC) in/on: (i) garden beets (1993; MRIDs 42919703 and 42939701); (ii) spinach (1993; MRID 42919702); and (iii) sugar beet processed commodities (1993; MRID 42939702). The registrant additionally submitted data from a new sugar beet field trial (1993; MRID 42919701). These studies are evaluated in this document for adequacy in fulfilling residue chemistry data requirements for the reregistration of cycloate. The Conclusions and Recommendations stated in this document pertain only to the topics listed above. Other data requirements stated in the Cycloate Phase IV Reviews are not addressed herein.

The qualitative nature of cycloate residues in plants is adequately understood (CBRS No. 9028, DP Barcode D171952, 5/19/92, C. Olinger) based on acceptable metabolism studies on sugar

beets and spinach. The HED Metabolism Committee (see 5/18/92 memorandum of C. Olinger) has determined that the total toxic residues to be regulated include cycloate and the free and conjugated forms of its metabolites, 3-hydroxycycloate and 4-hydroxycycloate (stereoisomers included). The qualitative nature of cycloate residues in animals is not adequately understood. The requirements for poultry and ruminant metabolism studies remain outstanding.

Tolerances for residues of cycloate (*S*-ethyl cyclohexylethylthiocarbamate) in/on plant commodities are presently expressed in terms of cycloate *per se* [40 CFR §180.212]. Tolerances for animal commodities and food/feed additives have not been established. A GLC method with steam distillation and/or acid hydrolysis and flame ionization detection, listed in PAM, Vol. II as Method A, is adequate for enforcement and collection of data on residues of cycloate *per se* in/on plant commodities. The Agency (CBRS No. 9028, DP Barcode D171952, 5/19/92, C. Olinger) has determined that new residue analytical method(s) capable of determining cycloate and all regulated metabolites in/on plants must be developed. The analytical method(s) must include a hydrolysis step which is capable of releasing conjugated residues of *cis* and *trans* isomers of 3-hydroxycycloate and 4-hydroxycycloate.

There are no established or proposed Codex MRLs for cycloate residues. Therefore, there are no issues of compatibility with respect to current U.S. tolerances and Codex MRLs.

CONCLUSIONS AND RECOMMENDATIONS

Magnitude of the Residue in Garden Beets

1. The submitted data from trials conducted in NY, OR, TX, and WI indicate that the combined residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) were <0.25 ppm (the combined LOQ for these analytes) in/on each of four samples of garden beet tops and roots harvested 65-93 days following a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation at 1x the maximum registered rate for each soil type. The additional data from a trial conducted in a CA sandy soil, following similar treatment at 1x, indicate that the combined residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) were <0.31 ppm in/on tops and <0.95 ppm in/on roots. These data are not presently supported by storage stability data. The registrant has indicated that a 3-year storage stability study on garden beet tops and roots was initiated in 1993. CBRS requires storage stability data for only 22 months since samples from the current submissions were stored frozen for a maximum of 22 months prior to residue analysis.
2. The currently established tolerances (expressed as cycloate *per se*) of 0.05 ppm in/on the roots and tops of garden beets are too low. The registrant must propose tolerances for the combined residues of cycloate and its metabolites to be regulated in/on garden beet tops and roots. The available data would support tolerance levels of 1 and 0.5

ppm in/on garden beet tops and roots, respectively. The registrant should also revise their current label to propose a 65-day preharvest interval.

Magnitude of the Residue in Sugar Beets

3. The submitted data indicate that the combined residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) were <0.25 ppm (the combined LOQ for these analytes) in/on each of eight samples of treated sugar beet tops and roots harvested 126-182 days following a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation at 1x the maximum registered rate. These data are not presently supported by storage stability data. The registrant has indicated that a 3-year storage stability study on sugar beet tops and roots was initiated in 1993. CBRs requires storage stability data for only 15 months since samples from the current submission were stored frozen for a maximum of 15 months prior to residue analysis.
4. The available data are incomplete to satisfy the reregistration requirements regarding this guideline topic because no field residue data are available reflecting the use of a registered 10% granular (Roneet® 10-G, EPA Reg. No. 10182-177) formulation on sugar beets. According to EPA Guidance on Number and Location of Domestic Crop Field Trials issued 6/2/94 (E. Saito and E. Zager), granular formulations will generally require the full number of field trials regardless of what data are already available for other formulation classes. If the registrant wishes to support the G formulation, then the following additional data are required:
 - Data depicting residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) in/on sugar beet tops and roots following a single pre-plant broadcast soil-incorporated application of the 10% G formulation 4 lb ai/A. A total of 12 field trials should be distributed among Region V (5), Region VII (1), Region VIII (1), Region IX (1), Region X (2) and Region XI (2). Two independently composited samples from each trial are required.
5. The registrant must propose tolerances for the combined residues of cycloate and its metabolites to be regulated in/on sugar beet tops and roots. The registrant also needs adequate storage stability data, field residue data for the G formulation and a label revision to include an appropriate PHI.

Magnitude of the Residue in Sugar Beet Processed Commodities

6. The submitted sugar beet processing study is acceptable. The data indicate that the combined residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) concentrated 3.5x in molasses processed from sugar beet roots that received a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation at 2x. No concentration of residues was observed in pulp and sugar

processed from similarly treated sugar beet roots. These data are not presently supported by storage stability data. The registrant has indicated that a 3-year storage stability study on sugar beet processed commodities was initiated in 1993. CBRS requires storage stability data for only 8 months since processed sugar beet fractions from the current submission were stored frozen for a maximum of 8 months prior to residue analysis.

7. Based on a concentration factor of 3.5x, the registrant must propose a feed additive tolerance for the combined residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) in molasses when all the reregistration requirements for the RAC (sugar beet roots) and adequate supporting storage stability data have been submitted.

Magnitude of the Residue in Spinach

8. The submitted data indicate that the combined residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) ranged from <0.25 ppm (the combined LOQ for these analytes) to <0.31 ppm in/on each of five samples of spinach harvested 64-89 days following a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation at 1x the maximum registered rate. These data are not presently supported by storage stability data. The registrant has indicated that a 3-year storage stability study on spinach was initiated in 1993. CBRS requires storage stability data for only 18 months since samples from the current submission were stored frozen for a maximum of 18 months prior to residue analysis.
9. The currently established tolerance (expressed as cycloate *per se*) of 0.05 ppm in/on spinach is too low. The registrant must propose tolerances for the combined residues of cycloate and its metabolites to be regulated in/on spinach. The available data would support a tolerance level of 0.5 ppm. The registrant should also revise their current label to propose a 65-day preharvest interval.

DETAILED CONSIDERATIONS

Residue Analytical Methods

In conjunction with the submitted field residue studies for garden beets (1993; MRIDs 42919703 and 42939701), spinach (1993; MRID 42919702), and sugar beets (1993; MRID 42919701), and sugar beet processing study (1993; MRID 42939702), Zeneca, Inc. submitted descriptions along with concurrent recovery data of a GC/NPD method (designated by the registrant as Tentative Residue Analytical Method, TRAM) for the determination of cycloate and its 3-hydroxy and 4-hydroxy metabolites.

Briefly, residues in/on plant commodities are extracted by blending with 50% aqueous acetone. After filtering, an aliquot of the extract is chilled on an ice bath, vacuum-evaporated to remove acetone, and then hydrolyzed by refluxing with 1 N HCl for two hours. The hydrolyzed residues are partitioned into dichloromethane, chilled, evaporated to remove dichloromethane, and mixed with toluene. Residues in the toluene fraction are derivatized with heptafluorobutyric anhydride (HFBA) at 60-65 C for 15-20 minutes. The derivatization procedure converts hydroxycycloate metabolites to HFBA esters; unconjugated cycloate *per se* does not react with HFBA. The toluene fraction is then washed with water, dried with anhydrous sodium sulfate, and analyzed by capillary GC/NPD. Metabolites are identified by comparison of retention times with the retention times of the following reference standards: cycloate, trans-3-hydroxycycloate, cis-3-hydroxycycloate, trans-4-hydroxycycloate, and cis-4-hydroxycycloate. The reported limit of quantitation for each analyte is 0.05 ppm.

- Confirmation of metabolites identified by GC/NPD is achieved by replacing the NPD with a mass selective detector (MSD) operating in the selective ion monitoring mode (SIM). The GC/MSD method also may be used to verify metabolite identities in the presence of co-extractive interfering substances in the samples.

The registrant provided concurrent method recoveries, which were included with each field trial and processing study data submission. Untreated control samples of garden beets, sugar beets and processed commodities, and spinach were separately fortified with cycloate, trans- and cis-3-hydroxycycloate, and trans- and cis-4-hydroxycycloate at 0.05 ppm. These method recovery data are presented in Table 1. Sample calculations and representative chromatograms were provided. The submitted method is adequate for collecting data on residues of cycloate, 3-hydroxycycloate, and 4-hydroxycycloate in/on garden beets, sugar beets and processed commodities, and spinach.

CBRS has concluded that the total toxic residues to be regulated include cycloate and the free and conjugated forms of its metabolites, cis- and trans-3-hydroxycycloate and cis- and trans-4-hydroxycycloate. Therefore, new residue analytical method(s) capable of determining cycloate and all regulated metabolites in/on plants must be developed for enforcement purposes. The analytical method must include a hydrolysis step which is capable of releasing conjugated residues of cis and trans isomers of 3-hydroxycycloate and 4-hydroxycycloate.

Table 1. Concurrent method recoveries of cycloate, 3-hydroxycycloate, and 4-hydroxycycloate from commodities of garden beets, sugar beets, and spinach (GC/NPD; Zeneca, Inc. TRAM).

Matrix	Forti- fication (ppm)	No. of Samples	Percent Recoveries ^a				
			Cycloate	t-3HC	c-3HC	t-4HC	c-4HC
Garden Beets (MRIDs 42919703 and 42039701)							
Roots	0.05	5	88-122	91-125	83-141	93-115	96-124
	0.10	1	102	129	134	124	124
Tops	0.05	3	91-130	101-116	101-130	97-123	112-121
	0.10	1	99	85	105	92	110
Sugar Beets (MRID 42919701)							
Roots	0.05	3	94-99	85-98	90-100	93, 99 ^b	76, 91 ^b
Tops	0.05	3	94-113	84-115	101-115	90-93	93-99
	2.00	1	110	113	116	109	111
Sugar Beet Processed Commodities (MRID 42939702)							
Roots	0.05	1	109	108	120	114	120
	0.50	1	104	111	122	112	120
Pulp	0.05	1	83	95	104	105	106
	0.50	1	102	101	108	105	111
Molasses	0.05	1	91	99	111	90	85
	0.50	1	107	120	115	109	116
Sugar	0.05	1	76	81	90	72	74
	0.50	1	76	88	87	73	92
Spinach (MRID 42919702)							
Spinach	0.05	3	94-117	86-131	88-135	86-117	87-122

^a All values are the highest of duplicate or triplicate analyses.

^b Two samples only.

Storage Stability Data

No new storage stability data were included to support the subject field trials and processing studies. The registrant indicated that 3-year storage stability studies were initiated in 1993 to validate the field trials for garden beets, sugar beets, and spinach as well as sugar beet processing commodities.

Magnitude of the Residue in Garden Beets

Tolerances of 0.05 ppm have been established for residues of cycloate *per se* in/on the roots and tops of garden beets [40 CFR §180.212].

A REFs search conducted 1/11/94 and a LUIS Report dated 10/25/90 identified one cycloate end-use product registered for use on garden beets. The 6 lb/gal EC (Roneet® 6-E, EPA Reg. No. 10182-178, 6/4/93) formulation is registered for a single pre-plant soil-incorporated broadcast or band application to garden beets grown on sandy soils at 3 lb ai/A or on heavy soils at 4 lb ai/A. Application is made in 20-50 gal of water/A using ground equipment.

Zeneca, Inc. submitted data (1993; MRIDs 42939701 and 42919703) from five tests conducted in CA(1), NY(1), OR(1), TX(1), and WI(1) depicting the combined residues of cycloate and its metabolites [trans- and cis-3-hydroxycycloate (t-3HC and c-3HC, respectively) and trans- and cis-4-hydroxycycloate (t-4HC and c-4HC, respectively)] in/on the commodities of garden beets. The roots and tops of garden beets were collected 65-93 days following a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation. The test formulation was applied at 3 lb ai/A in CA (sandy soil type) and at 4 lb ai/A in NY and OR (silt loam soil type), TX (sandy clay loam soil type), and WI (silty clay loam soil type). The applied rates are equivalent to 1x the maximum registered rate for each soil type. A minimum of 24 root samples and 12 top samples were harvested from each test location. All samples were frozen within four hours of harvest and shipped frozen to the Environmental Chemistry Section of Zeneca, Inc. (Richmond, CA) where they were stored frozen at -15 C prior to analysis. The total frozen storage interval from harvest to analysis was 459-665 days (~15-22 months).

Residues of cycloate and its metabolites were determined using the GC/NPD method previously described. The results of the field trials are presented in Table 2. Five control samples of garden beet tops and roots each bore apparent combined residues of <0.25 ppm (the combined LOQ for the analytes).

Geographic representation is adequate since the test states of CA(6%), NY(32%), OR(11%), TX(8%), and WI(30%) accounted for ~90% of the 1982 U.S. garden beet production (1982 *Census of Agriculture, Vol. 1, Part 51, p. 337*).

Table 2. Residues of cycloate and its metabolites of concern in/on the roots and tops of garden beets harvested 65-93 days following a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation at 1x.

State ^a	Rate (ai/A)	Uncorrected Residues (ppm) ^b					Total
		Cycloate	t-3HC	c-3HC	t-4HC	c-4HC	
Roots							
CA	3	<0.05	<0.05	0.11	<0.05	<0.05	<0.31
NY	4	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25
OR	4	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25
TX	4	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25
WI	4	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25
Tops							
CA	3	<0.05	0.44	0.30	0.11	<0.05	<0.95
NY	4	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25
OR	4	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25
TX	4	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25
WI	4	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25

^a Test site soils: CA, sandy; NY and OR, silt loam; TX, sandy clay loam, and WI, silty clay loam.

^b Values presented are the highest of duplicate analyses.

The submitted data from trials conducted in NY, OR, TX, and WI indicate that the combined residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) were <0.25 ppm (the combined LOQs for these analytes) in/on each of four samples of garden beet tops and roots harvested 65-93 days following a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation at 1x the maximum registered rate for each soil type. The additional data from a trial conducted in a CA sandy soil, following similar treatment at 1x, indicate that the combined residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) were <0.31 ppm in/on tops and <0.95 ppm in/on roots. These data are not presently supported by storage stability data. The registrant has indicated that a 3-year storage stability study on garden beet tops and roots was initiated in 1993. CBRS requires storage stability data for only 22 months since samples from the current submissions were stored frozen for a maximum of 22 months prior to residue analysis.

The currently established tolerances (expressed as cycloate *per se*) of 0.05 ppm in/on the roots and tops of garden beets are too low. Pending submission of acceptable storage stability data to validate the current residue trials, the registrant must propose tolerances for the combined residues of cycloate and its metabolites to be regulated in/on garden beet tops and roots. The available data would support tolerance levels of 1 and 0.5 ppm in/on garden beet tops and roots, respectively.

Magnitude of the Residue in Sugar Beets

Tolerances of 0.05 ppm have been established for residues of cycloate *per se* in/on the roots and tops of sugar beets [40 CFR §180.212].

A REFs search conducted 1/11/94 and a LUIS Report dated 10/25/90 identified two cycloate end-use product registered for use on sugar beets. The 10% G (Roneet® 10-G, EPA Reg. No. 10182-177, 9/23/85) and the 6 lb/gal EC (Roneet® 6-E, EPA Reg. No. 10182-178, 6/4/93) formulations are registered for a single pre-plant soil-incorporated broadcast or band application to sugar beets grown on sandy soils at 3 lb ai/A or on heavy soils at 4 lb ai/A. The EC formulation is also registered for a single late fall application at 4 lb ai/A in ID, MN, MT, ND, OR, WY, and WA before the ground freezes, with the application to be made in 20-50 gal of water/A using ground equipment.

The Cycloate Phase IV Reviews (S. Funk, 12/20/90) concluded that acceptable data are available depicting the magnitude of residues of cycloate *per se* in/on sugar beet commodities following application of the EC formulation according to the maximum registered use patterns. No additional field residue data were required unless plant metabolism studies identify additional metabolites that need to be regulated. Plant metabolism has now been adequately delineated. The residues of concern are cycloate and the free and conjugated forms of its metabolites, 3-hydroxycycloate and 4-hydroxycycloate. Subsequently, a new sugar beet field residue study has been submitted by the registrant. These data are discussed below.

Zeneca, Inc. submitted data (1993; MRID 42919701) from eight tests conducted in CA(1), CO(1), ID(1), MI(1), MN(1), MT(1), NE(1), and ND(1) depicting the combined residues of cycloate and its metabolites [trans- and cis-3-hydroxycycloate (t-3HC and c-3HC, respectively) and trans- and cis-4-hydroxycycloate (t-4HC and c-4HC, respectively)] in/on the commodities of sugar beets. The roots and tops of sugar beets were harvested 126-182 days following a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation at 3.9-4.0 lb ai/A (1x the maximum registered rate) in 10-21 gal of water/A using ground equipment. The treated plots were planted with sugar beets on the same day of cycloate application. A minimum of 12 control and 12 treated plants were harvested from each test site at crop maturity. All samples were stored frozen within six hours of harvest and shipped frozen to the Environmental Chemistry Section of Zeneca, Inc. (Richmond, CA) where they were stored frozen at -15 C prior to analysis. The total frozen storage interval from harvest to analysis was 389-455 days (~13-15 months).

Residues of cycloate and its metabolites were determined using the GC/NPD method previously described. The combined uncorrected residues of cycloate, t-3HC, c-3HC, t-4HC, and c-4HC were <0.25 ppm (the combined LOQs for these analytes) in/on each of eight samples of treated sugar beet tops and roots. Eight control samples of sugar beet tops and roots each bore apparent combined residues <0.25 ppm.

Geographic representation is adequate since the test states of CA(13%), CO(3%), ID(18%), MI(9%), MN(22%), MT(5%), NE(6%), and ND(13%) accounted for ~90% of the 1991 U.S. sugar beet production (*Agricultural Statistics, 1991, USDA*).

The submitted data indicate that the combined residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) were <0.25 ppm (the combined LOQs for these analytes) in/on each of eight samples of treated sugar beet tops and roots harvested 126-182 days following a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation at 1x the maximum registered rate. These data are not presently supported by storage stability data. The registrant has indicated that a 3-year storage stability study on sugar beet tops and roots was initiated in 1993. CBRS requires storage stability data for only 15 months since samples from the current submission were stored frozen for a maximum of 15 months prior to residue analysis.

The available data are incomplete to satisfy the reregistration requirements regarding this guideline topic because no field residue data are available reflecting the use of a registered 10% granular (Roneet® 10-G, EPA Reg. No. 10182-177) formulation on sugar beets. According to EPA Guidance on Number and Location of Domestic Crop Field Trials issued 6/2/94 (E. Saito and E. Zager), granular formulations will generally require the full number of field trials regardless of what data are already available for other formulation classes. If the registrant wishes to support the G formulation, then the following additional data are required:

- Data depicting residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) in/on sugar beet tops and roots following a single pre-plant broadcast soil-incorporated application of the 10% G formulation 4 lb ai/A. A total of 12 field trials should be distributed among Region V (5), Region VII (1), Region VIII (1), Region IX (1), Region X (2) and Region XI (2). Two independently composited samples from each trial are required.

Following submission of adequate storage stability data and field residue data reflecting use of a G formulation, the registrant must propose tolerances for the combined residues of cycloate and its metabolites to be regulated in/on sugar beet tops and roots.

Magnitude of the Residue in Sugar Beet Processed Commodities

No tolerances have been established for residues of cycloate in/on sugar beet processed commodities. See "Magnitude of the Residue in Sugar Beets" section for registered use patterns of cycloate.

Zeneca, Inc. submitted a sugar beet processing study (1993; MRID 42939702) conducted in CA. Sugar beets were harvested 196 days following a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation at 8 lb ai/A (2x the maximum

registered rate) in 30 gal of water/A using ground equipment. [CBRS notes that the maximum theoretical concentration of sugar from the processing (based on separation into components) of sugar beets is 12.5x (see 1/93 memorandum on Maximum Theoretical Concentration Factors)]. At crop maturity, 300 lbs of sugar beets were separately harvested from the control and treated plots. Twelve root sub-samples were removed from each bulk sample and shipped frozen to the Environmental Chemistry Section of Zeneca, Inc. (Richmond, CA) for residue analysis. The remaining samples were shipped frozen to the processor (William J. Englar & Associates, Inc., Moses Lake, WA) where they were processed into pulp, sugar, and molasses. The registrant provided flow charts of the processing procedures which according to the registrant were representative of typical commercial practices; in addition data concerning the maximum theoretical concentration factor of sugar beet fractions, based on weight ratio of starting sugar beet roots to processed products, were provided. The processed fractions were shipped frozen to the analytical laboratory for residue analysis. The total frozen storage interval from harvest to analysis was 235-249 days (~8 months).

Residues of cycloate and its metabolites were determined using the GC/NPD method previously described. The results of the processing study are presented in Table 3. The apparent combined residues of cycloate and its metabolites were <0.25 ppm (the combined LOQs for the analytes) in/on each sample of untreated sugar beet roots, pulp, sugar, and molasses.

Table 3. Residues of cycloate and its metabolites of concern in/on the processed fractions of sugar beets treated with a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation at 2x.

Commodity	Uncorrected Residues (ppm) ^a						Concentration/R eduction factor	Theoretical Concentration Factor ^b
	Cycloate	t-3HC	c-3HC	t-4HC	c-4HC	Total		
Roots	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25	--	
Pulp	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25	--	27
Molasses	<0.05	0.19	0.38	0.17	0.08	<0.87	<3.5	117
Sugar	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25	--	81

^a Values are the highest of duplicate sample analyses.

^b Calculated by registrant based on weight ratio of starting sugar beet roots to processed products.

The submitted sugar beet processing study is acceptable. The data indicate that the combined residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) concentrated 3.5x in molasses processed from sugar beet roots that received a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation at 2x. No concentration of residues was observed in pulp and sugar processed from similarly treated sugar beet roots. These data are not presently supported by storage stability data. The registrant has indicated that a 3-year storage stability study on sugar beet processed commodity was initiated in 1993. CBRS requires storage stability data for only 8 months since processed sugar beet fractions from the current submission were stored frozen for a maximum of 8 months prior to residue analysis.

Based on a concentration factor of 3.5x, the registrant must propose a feed additive tolerance for the combined residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) in molasses when all the reregistration requirements for the RAC (sugar beet roots) and adequate supporting storage stability data have been submitted.

Magnitude of the Residue in Spinach

A tolerance of 0.05 ppm has been established for residues of cycloate *per se* in/on spinach [40 CFR §180.212].

A REFs search conducted 1/11/94 and a LUIS Report dated 10/25/90 identified one cycloate end-use product registered for use on spinach. The 6 lb/gal EC (Roneet® 6-E, EPA Reg. No. 10182-178, 6/4/93) formulation is registered for a single pre-plant soil-incorporated broadcast or band application to spinach grown in AR, CT, DE, MA, MD, ME, MS, NH, NJ, NY, OH, OK, PA, TX, VA, VT, and western TN at rates of 3 lb ai/A for sandy soils and 4 lb ai/A for heavy soils. Application is made in 20-50 gal of water/A using ground equipment.

Zeneca, Inc. submitted data (1993; MRID 42919702) from five tests conducted in AR(1), CA(2), MD(1), and TX(1) depicting the combined residues of cycloate and its metabolites [trans- and cis-3-hydroxycycloate (t-3HC and c-3HC, respectively) and trans- and cis-4-hydroxycycloate (t-4HC and c-4HC, respectively)] in/on spinach. Spinach were harvested 64-89 days following a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation. The test formulation was applied at 3 and 4 lb ai/A (0.75 and 1x the maximum registered rate, respectively) in CA; the test substance was applied at 4 lb ai/A (1x) in AZ, MD, and TX. A minimum of 12 control and 12 treated plants were harvested from each site at crop maturity. All samples were frozen or stored on dry/blue ice within four hours of harvest. Samples were shipped frozen to the Environmental Chemistry Section of Zeneca, Inc. (Richmond, CA) where they were stored at < -15 C prior to analysis. The total frozen storage interval from harvest to analysis was 387-547 days (~13-18 months).

Residues of cycloate and its metabolites were determined using the GC/NPD method previously described. The results of the field trials are presented in Table 4. Four control samples of spinach each bore apparent combined residues < 0.25 ppm (the combined LOQs for the analytes).

Geographic representation is adequate since the test states of AR(4%), CA(25%), NJ(6%), and TX(25%) represent the major spinach-growing areas of the U.S. (1982 *Census of Agriculture*, Vol. 1, Part 51, p. 352).

Table 4. Residues of cycloate and its metabolites of concern in/on spinach harvested 64-89 days following a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation at 1x.

State	Rate (lb ai/A)	Uncorrected Residues (ppm) ^a					Total
		Cycloate	t-3HC	c-3HC	t-4HC	c-4HC	
AR	4	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25
CA	3	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25
CA	4	<0.05	<0.05	<0.05	<0.05	0.11	<0.31
NJ	4	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25
TX	4	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25

^a Values presented are the highest of duplicate analyses.

The submitted data indicate that the combined residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) ranged from <0.25 ppm (the combined LOQs for these analytes) to <0.31 ppm in/on each of five samples of spinach harvested 64-89 days following a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation at 1x the maximum registered rate. These data are not presently supported by storage stability data. The registrant has indicated that a 3-year storage stability study on spinach was initiated in 1993. CBRS requires storage stability data for only 18 months since samples from the current submissions were stored frozen for a maximum of 18 months prior to residue analysis.

The currently established tolerance (expressed as cycloate *per se*) of 0.05 ppm in/on spinach is too low. Pending submission of acceptable storage stability data to validate the current residue trials, the registrant must propose tolerances for the combined residues of cycloate and its metabolites to be regulated in/on spinach. The available data would support a tolerance level of 0.5 ppm.

EPA MEMORANDA CITED IN THIS DOCUMENT

CBRS No.: None
Subject: Cycloate Phase IV Reviews
From: S. Funk
To: A. Rathman and E. Zager
Dated: 12/20/90
MRID(s): None

CBRS No.: 9028
Subject: Reregistration Phase V: Cycloate Plant Metabolism Studies; Chemical No. 41301; Case No. 2125; DP Barcode D171952.
From: C.L. Olinger
To: E. Dobbins and L. Deluise
Dated: 5/19/92
MRID(s): 420903-01 and -02

MASTER RECORD IDENTIFICATION NUMBERS

Citations for the MRID documents referred to in this review are presented below.

42919701 Grant, C.L. and Herman, R. S. (1993) RO-NEET®: Magnitude of the Residue Study for Cycloate on Sugar Beets; Spring Application. Study Number CYCL-92-MR-03; Report Number RR 93-038B. Unpublished study prepared by ZENECA Ag Products, Richmond, CA. 203 p.

42919702 Grant, C.L. and Herman, R. S. (1993) RO-NEET®: Magnitude of the Residue Study for Cycloate on Spinach; Fall Planting. Study Number CYCL-91-MR-01; Report Number RR 93-036B. Unpublished study prepared by ZENECA Ag Products, Richmond, CA. 141 p.

42919703 Grant, C.L. and Herman, R. S. (1993) RO-NEET®: Magnitude of the Residue Study for Cycloate on Table Beets. Study Number CYCL-91-MR-02; Report Number RR 93-037B. Unpublished study prepared by ZENECA Ag Products, Richmond, CA. 150 p.

42939701 Grant, C.L. and Herman, R. S. (1993) RO-NEET®: Magnitude of the Residue Study for Cycloate on Table Beets. Study Number CYCL-92-MR-01; Report Number RR 93-063B. Unpublished study prepared by ZENECA Ag Products, Richmond, CA. 98 p.

42939702 Grant, C.L. and Herman, R. S. (1993) RO-NEET®: Residue Processing Study for Cycloate on Sugar Beets. Study Number CYCL-92-PR-01; Report Number RR 93-059B. Unpublished study prepared by ZENECA Ag Products, Richmond, CA. 92 p.



Oregon

John A. Kitzhaber, M.D., Governor

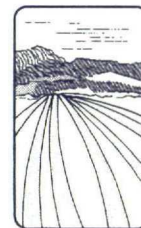
02-J. Tompkins

Department of Agriculture

635 Capitol Street NE
Salem, OR 97301-2532

October 15, 2001

Jim Tompkins- Product Manager (25)
Registration Division - Herbicide Branch
Office of Pesticide Programs (7505C)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Ave. NW
Washington, D.C. 20460-0001



RE: Amended Label
TRI AG, INC./ RO-NEET 6-E (a.i. cycloate)
EPA Reg. No. 73637-5 EPA SLN No. OR-010023
Site- Spinach, PHI - 45 Days

Enclosed is an amended SLN label for the use of TRI AG, INC./RO-NEET 6-E on spinach grown in the State of Oregon. The amended label includes a 45 day PHI as requested by EPA, in a letter dated September 26, 2001(enclosed). The September 26 letter supersedes a letter in which a 65 day PHI was requested (enclosed letter dated September 11).

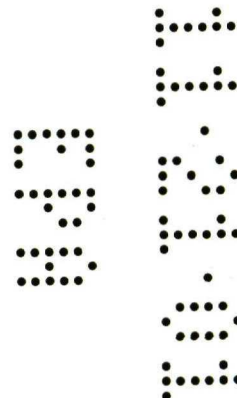
In addition, as a matter of courtesy, I have enclosed a copy of the distributor SLN label, Cedar Chemical Corporation/RO-NEET 6-E, EPA SLN No. OR-010023. Please note, it is acknowledged that TRI AG, INC. is the Section 24(c) registrant. When TRI AG, INC. selects to cancel the RO-NEET SLN registration (OR-010023), the Cedar Chemical label will automatically become invalid.

Bob McReynolds of Oregon State University and TRI AG, INC./Cedar Chemical Co. will develop the residue studies mandated by EPA. The exact details are still being discussed.

Thank you for assisting a small acreage, but important crop in the State of Oregon. If you have any questions, please do not hesitate to contact me.

Sincerely,

Rose Kachadoorian
Registration Specialist, Pesticides Division
Oregon Department of Agriculture
503/986-4651 Phone , 503/986-4735 Fax
Email Address: rkachado@oda.state.or.us



CC: George Robinson, Idaho Dept. of Ag.
Fred Salzman, IR-4
Wendy Sue Wheeler, Washington State Dept. of Ag.
Jeanine Betsher, Cedar Chemical Corp.
Bob McReynolds, OSU
Mr. Jud Hedine, Chiquita Processed Foods
Karla Chambers/Andy Bennett, Stahlbush Island Farms, Inc.

SEP 24 1993



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

SEP 26 2001

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Ms. Rose Kachadoorian
Registration Specialist
Oregon Department of Agriculture
635 Capitol Street, NE
Salem, OR 97301-2532

SUBJECT: RO-NEET 6-E, SLN No. OR010023

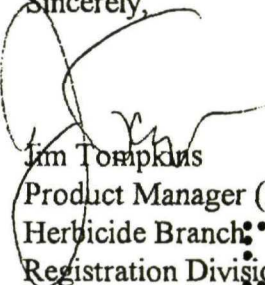
Dear Ms. Kachadoorian:

In a letter dated September 5, 2001 the SLN referred to above was recommended for disapproval. The SLN No. OR010023, submitted under Section 24C of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) is acceptable provided you:

1. Put a 45-day preharvest interval on the label.
2. Submit residue studies reflecting the current use pattern conducted in accordance with current Agency guidelines within 36 months from the date of this letter.

If you have any questions concerning this letter, please contact me at (703) 305-5697.

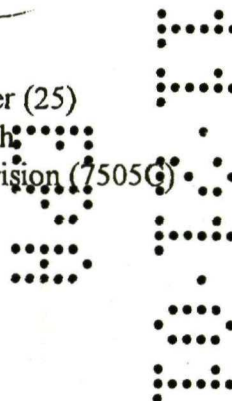
Sincerely,


Jim Tompkins
Product Manager (25)
Herbicide Branch
Registration Division (7505G)

RECEIVED

OCT 01 2001

AGRICULTURE
PESTICIDE SECTION



To: Tompkins.Jim@epamail.epa.gov
From: Rose Kachadoorian <rkachado@mh.oda.state.or.us>
Subject: Ro-neet on spinach
Cc: bob.mcreynolds@orst.edu, Jeanine Betsher <jbetsher@prodigy.net>, "Wheeler, Wendy Sue (AGR)" <WSWheeler@agr.wa.gov>, salzman@AESOP.RUTGERS.EDU
Bcc:
X-Attachments:

Jim,

The purpose of this email is to share with you: (1) some background information concerning the cropping patterns of spinach in both Western and Eastern Oregon, and (2) to obtain information from you about why a 65 day PHI is desired by EPA for the use of Ro-neet 6E (cycloate) on spinach.

In Western Oregon (west of the Cascade Mt. Range), spinach is grown for the fresh market, and is planted as a continuous crop every 3-7 days. The spinach is harvested 45-65 days later depending on the weather conditions. The planting begins in May and ends sometime in October. In Eastern Oregon, the crop is grown for the processing market (primarily canning). Spinach is planted August 8 through 18, and mechanical harvesting is initiated approx. October 8.

Neither the Zeneca/Ro-neet 6E label (EPA Reg. No. 10182-178), nor the Cedar Chemical/Ro-neet 6E label (EPA Reg. No. 73637-5) have PHIs listed for any of the crops, including spinach. At first the lack of PHIs appeared odd, but then I recalled that it seems like EPA often does not indicate PHIs when the chemical can not be detected within a reasonable proximity to harvest. To investigate if my assumption might be correct, I re-reviewed the data originally submitted to the Department in 1994 (admittedly some of the data is quite old). It appears from the studies, that cycloate residue was never detected on the harvested spinach, even if the samples were collected only 21 days after application. Hence, possibly the reason EPA never indicated a PHI on the Section 3 label.

The recent 65 day PHI proposed by EPA would make this product unusable to the spinach growers, esp. the fresh market growers. Unlike many other crops, spinach growers have few options. In a recent review of our computer data base, the following active ingredients may be use in spinach fields: glyphosate, copper, sethoxdim, pelargonic acid and phenmedipham. I did not review the actual labels of these products. Based on the data and the need for this product, the Oregon Department of Agriculture is asking you to reconsider the proposed PHI of 65 days. You may be receiving a call from IR-4 concerning the reconsideration of this matter.

The Department will strongly consider funding a residue study (through our minor crops program) on spinach in 2002. Oregon State University is interested in supporting the use of this material on spinach, and will probably be involved in the study.

I will be out of the office on 9/24, but look forward to discussing this matter with you after that time. Thank you for your assistance.

Rose Kachadoorian
24(c) Registration Specialist
Pesticides Division
Oregon Department of Agriculture
635 Capitol St. NE
Salem, OR 97301-2532

Email: rkachado@oda.state.or.us

503/986-4651 Phone, 503/986-4735 Fax



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

SEP 5 2001

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

RECEIVED

SEP 11 2001

AGRICULTURE
PESTICIDE SECTION

Ms. Rose Kachadoorian
Registration Specialist
Oregon Department of Agriculture
635 Capitol Street, NE
Salem, OR 97301-2532

SUBJECT: Notice of Intent to Disapprove
RO-NEET 6-E, SLN No. OR010023
Your Submission Dated June 27, 2001

Dear Ms. Kachadoorian:

The State of Oregon issued a State Registration SLN No. OR010023, on June 27, 2001 under Section 24C of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). This application was issued for use on spinach to control weeds.

Decision

The Agency concludes that EPA SLN No. OR010023 may be disapproved for the reasons provided below. If the State can satisfy the Agency's concerns set forth below, this notification may be withdrawn. Therefore, you should take immediate steps to consult with the appropriate Agency designee identified below and respond to this notice.

Reasons for Disapproval

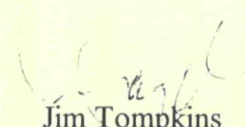
1. Revise label to include a 65-day preharvest interval.

Response

You should respond to the deficiencies described above in writing within 10 days of receipt of this notice. You may also request a consultation with the Agency prior to a final disapproval decision. Failure to respond in a timely and adequate manner may result in disapproval of EPA SLN No. OR010023.

If you have any questions concerning this letter, please contact me at (703) 305-5697.

Sincerely,


Jim Tompkins
Product Manager (25)
Herbicide Branch
Registration Division (7505C)

PRODUCT INFORMATION

CEDAR CHEMICAL CORP.



REGISTRATION FOR SPECIAL LOCAL NEED
FOR DISTRIBUTION AND USE ONLY WITHIN THE STATE OF OREGON

RO-NEET® 6-E

EPA Reg. No. 73637-5-56077

EPA SLN No. OR-010023

This label valid until December 31, 2004 or until otherwise amended, withdrawn, canceled, or suspended.

FOR USE IN SPINACH

ACTIVE INGREDIENT:

S-ethyl cyclohexylethylthiocarbamate 73.9%

INERT INGREDIENTS: 26.1%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT

FIRST AID: If a known exposure occurs or is suspected, immediately start the recommended procedures below. Simultaneously contact a Poison Control Center, a physician, or the nearest hospital. Describe the situation and follow the advice given.

IF SWALLOWED: Immediately give large quantities of water but DO NOT induce vomiting. *This product contains hydrocarbon solvent.* If vomiting does occur, give fluids again. Have a physician determine if condition of patient will permit evacuation of stomach. DO NOT give anything by mouth to an unconscious person. Call a physician immediately.

IF IN EYES: Hold eyelids apart and flush eyes with large amounts of running water for 15 minutes. Get medical attention if irritation occurs.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED: Remove to fresh air. Get medical attention if respiratory irritation occurs.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

HARMFUL IF SWALLOWED. Avoid contact with skin, eyes, and clothing. Avoid contamination of feed or food.

Personal Protective Equipment (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category E on an EPA chemical resistance category selection chart.

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical-resistant gloves, such as barrier laminate or nitrile rubber or neoprene rubber or viton
- Shoes plus socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

REVISED
OCT 15 2001

Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 12 hours. Exception: If the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

PPE required for early entry into treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

- Coveralls
- Chemical-resistant gloves, such as barrier laminate or nitrile rubber or neoprene rubber or viton
- Shoes plus socks

SPINACH: Apply a surface broadcast application with ground application equipment prior to planting. Apply 0.34 to 0.50 gallons RO-NEET 6-E (2-3 lbs. ai) per acre on sandy mineral soils only in a minimum of 20 gallons of water. Immediately (within minutes) after application thoroughly mix RO-NEET 6-E into the soil to a depth of 2 to 3 inches using a finishing disk, harrow, rolling cultivator or similar implement capable of providing uniform incorporation. Do NOT harvest spinach for 45 days following application of this product.

WEEDS CONTROLLED: For List of Weeds Controlled See EPA-registered RO-NEET 6-E Label.

Do not apply this product through any type of irrigation system.

Special Conditions and Disclaimer for use of RO-NEET on Spinach.

Cedar intends that this Section 24(c) label be distributed only to end users and/or growers (and/or applicators acting on behalf of growers) who agree to the terms and conditions below, and agree in writing to the terms and conditions required including a waiver and release from all liability and indemnification by the user and/or grower of Cedar and others for failure to perform and crop damage from the use of RO-NEET 6-E on spinach grown for canning. If such terms and conditions are unacceptable, return RO-NEET 6-E at once unopened.

This product when used on spinach grown for canning may lead to crop injury, loss, or damage. Cedar recommends that the user and/or grower test this product in order to determine its suitability for such intended use. Cedar makes this product available to the user and/or grower solely to the extent the benefit and utility, in the sole opinion of the user and/or grower, outweigh, the extent of potential injury associated with the use of this product. The decision to use or not to use this product must be made by each individual user and/or grower on the basis of possible crop injury from RO-NEET 6-E, the severity of weed infestation, the cost of alternative weed controls, and other factors. Because of the risk of failure to perform or crop damage, all such use is at the user's and/or grower's risk.

This labeling must be in the possession of the user at the time of pesticide application.

Follow all applicable directions, restrictions and precautions on the EPA-registered label.

IMPORTANT: Read the entire Directions for Use and the Conditions of Sale and Warranty before using this product.

**CONDITIONS OF SALE
AND LIMITATION OF WARRANTY AND LIABILITY**

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product should be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of Cedar or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold Cedar and Seller harmless for any claims relating to such factors.

Cedar warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or Cedar, and Buyer and User assume the risk of any such use. Cedar MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

In no event shall Cedar or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF Cedar AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF Cedar OR SELLER, THE REPLACEMENT OF THE PRODUCT.

Cedar and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sale and limitations of warranty and of liability, which may not be modified except by written agreement signed by a duly authorized representative of Cedar.

RO-NEET 6-E is a trademark of Cedar Chemical Corp.
24(c) Registrant: TRI AG, INC.

EPA SLN NO: OR-010023

PRODUCT INFORMATION

TRI AG, INC.

**REGISTRATION FOR SPECIAL LOCAL NEED
FOR DISTRIBUTION AND USE ONLY WITHIN THE STATE OF OREGON**

RO-NEET® 6-E

EPA Reg. No. 73637-5

EPA SLN No. OR-010023

This label valid until December 31, 2004 or until otherwise amended, withdrawn, canceled, or suspended.

FOR USE ON SPINACH

ACTIVE INGREDIENT:

S-ethyl cyclohexylethylthiocarbamate 73.9%

INERT INGREDIENTS: 26.1%

TOTAL 100.0%

REVISED
OCT 15 2001

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT

FIRST AID: If a known exposure occurs or is suspected, immediately start the recommended procedures below. Simultaneously contact a Poison Control Center, a physician, or the nearest hospital. Describe the situation and follow the advice given.

IF SWALLOWED: Immediately give large quantities of water but DO NOT induce vomiting. *This product contains hydrocarbon solvent.* If vomiting does occur, give fluids again. Have a physician determine if condition of patient will permit evacuation of stomach. DO NOT give anything by mouth to an unconscious person. Call a physician immediately.

IF IN EYES: Hold eyelids apart and flush eyes with large amounts of running water for 15 minutes. Get medical attention if irritation occurs.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED: Remove to fresh air. Get medical attention if respiratory irritation occurs.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

HARMFUL IF SWALLOWED. Avoid contact with skin, eyes, and clothing. Avoid contamination of feed or food.

Personal Protective Equipment (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category E on an EPA chemical resistance category selection chart.

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical-resistant gloves, such as barrier laminate or nitrile rubber or neoprene rubber or viton
- Shoes plus socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry to treated areas during the restricted-entry interval (REI) of 12 hours. Exception: If the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

PPE required for early entry into treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

- Coveralls
- Chemical-resistant gloves, such as barrier laminate or nitrile rubber or neoprene rubber or viton
- Shoes plus socks

SPINACH: Apply a surface broadcast application with ground application equipment prior to planting. Apply 0.34 to 0.50 gallons RO-NEET 6-E (2-3 lbs. ai) per acre on sandy mineral soils only in a minimum of 20 gallons of water. Immediately (within minutes) after application thoroughly mix RO-NEET 6-E into the soil to a depth of 2 to 3 inches using a finishing disk, harrow, rolling cultivator or similar implement capable of providing uniform incorporation. Do NOT harvest spinach for 45 days following application of this product.

WEEDS CONTROLLED: For List of Weeds Controlled See EPA-registered RO-NEET 6-E Label.

Do not apply this product through any type of irrigation system.

Special Conditions and Disclaimer for use of RO-NEET on Spinach.

TRI AG, INC. intends that this Section 24(c) label be distributed only to end users and/or growers (and/or applicators acting on behalf of growers) who agree to the terms and conditions below, and agree in writing to the terms and conditions required including a waiver and release from all liability and indemnification by the user and/or grower of TRI AG, INC. and others for failure to perform and crop damage from the use of RO-NEET 6-E on spinach grown for canning. If such terms and conditions are unacceptable, return RO-NEET 6-E at once unopened.

This product when used on spinach grown for canning may lead to crop injury, loss, or damage. TRI AG, INC. recommends that the user and/or grower test this product in order to determine its suitability for such intended use. TRI AG, INC. makes this product available to the user and/or grower solely to the extent the benefit and utility, in the sole opinion of the user and/or grower, outweigh, the extent of potential injury associated with the use of this product. The decision to use or not to use this product must be made by each individual user and/or grower on the basis of possible crop injury from RO-NEET 6-E, the severity of weed infestation, the cost of alternative weed controls, and other factors. Because of the risk of failure to perform or crop damage, all such use is at the user's and/or grower's risk.

This labeling must be in the possession of the user at the time of pesticide application.

Follow all applicable directions, restrictions and precautions on the EPA-registered label.

IMPORTANT: Read the entire Directions for Use and the Conditions of Sale and Warranty before using this product.

**CONDITIONS OF SALE
AND LIMITATION OF WARRANTY AND LIABILITY**

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24(c) Registrant: TRI AG

EPA SLN NO: OR-010023

PRODUCT INFORMATION

TRI AG, INC.

**REGISTRATION FOR SPECIAL LOCAL NEED
FOR DISTRIBUTION AND USE ONLY WITHIN THE STATE OF OREGON**

RO-NEET® 6-E

EPA Reg. No. 73637-5

EPA SLN No. OR-010023

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FOR USE ON SPINACH

ACTIVE INGREDIENT:

S-ethyl cyclohexylethylthiocarbamate 73.9%

INERT INGREDIENTS: 26.1%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT

FIRST AID: If a known exposure occurs or is suspected, immediately start the recommended procedures below. Simultaneously contact a Poison Control Center, a physician, or the nearest hospital. Describe the situation and follow the advice given.

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IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

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Personal Protective Equipment (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category E on an EPA chemical resistance category selection chart.

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical-resistant gloves, such as barrier laminate or nitrile rubber or neoprene rubber or viton
- Shoes plus socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

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Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

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DIRECTIONS FOR USE

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24(c) Registrant: TRI AG

EPA SLN NO: OR-010023

PRODUCT INFORMATION

TRI AG, INC.

**REGISTRATION FOR SPECIAL LOCAL NEED
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RO-NEET® 6-E

EPA Reg. No. 73637-5

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WEEDS CONTROLLED: For List of Weeds Controlled See EPA-registered RO-NEET 6-E Label.

Do not apply this product through any type of irrigation system.

Special Conditions and Disclaimer for use of RO-NEET on Spinach.

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24(c) Registrant: TRI AG

EPA SLN NO: OR-010023

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 26 2001

Ms. Rose Kachadoorian
Registration Specialist
Oregon Department of Agriculture
635 Capitol Street, NE
Salem, OR 97301-2532

SUBJECT: RO-NEET 6-E, SLN No. OR010023

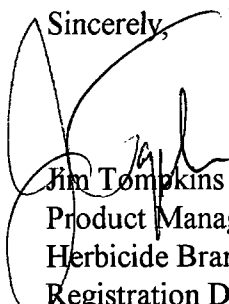
Dear Ms. Kachadoorian:

In a letter dated September 5, 2001 the SLN referred to above was recommended for disapproval. The SLN No. OR010023, submitted under Section 24C of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) is acceptable provided you:

1. Put a 45-day preharvest interval on the label.
2. Submit residue studies reflecting the current use pattern conducted in accordance with current Agency guidelines within 36 months from the date of this letter.

If you have any questions concerning this letter, please contact me at (703) 305-5697.

Sincerely,


Jim Tompkins
Product Manager (25)
Herbicide Branch
Registration Division (7505C)

CONCURRENCES

SYMBOL ▶	7505C							
SURNAME ▶	MINOR, E.							
DATE ▶	Sep 26, 2001							

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 5 2001

Ms. Rose Kachadoorian
Registration Specialist
Oregon Department of Agriculture
635 Capitol Street, NE
Salem, OR 97301-2532

SUBJECT: Notice of Intent to Disapprove
RO-NEET 6-E, SLN No. OR010023
Your Submission Dated June 27, 2001

Dear Ms. Kachadoorian:

The State of Oregon issued a State Registration SLN No. OR010023, on June 27, 2001 under Section 24C of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). This application was issued for use on spinach to control weeds.

Decision

The Agency concludes that EPA SLN No. OR010023 may be disapproved for the reasons provided below. If the State can satisfy the Agency's concerns set forth below, this notification may be withdrawn. Therefore, you should take immediate steps to consult with the appropriate Agency designee identified below and respond to this notice.

CONCURRENCES

SYMBOL ▶	7505C							
SURNAME ▶	MINOR, E.							
DATE ▶	Sep 5, 2001							

Reasons for Disapproval

1. Revise label to include a 65-day preharvest interval.

Response

You should respond to the deficiencies described above in writing within 10 days of receipt of this notice. You may also request a consultation with the Agency prior to a final disapproval decision. Failure to respond in a timely and adequate manner may result in disapproval of EPA SLN No. OR010023.

If you have any questions concerning this letter, please contact me at (703) 305-5697.

Sincerely,



Jim Tompkins
Product Manager (25)
Herbicide Branch
Registration Division (7505C)

9/5/2001
1. Clearance 2 to 1000 in sprayer
O.K. for now.
2. need a 65 day PHI - see
enclosed memo from NED.
jth

See p 6
65 day PHB for spinach

MEMORANDUM

SUBJECT: Cycloate. Case No. 2125. Magnitude of Residue Studies: Garden Beets, Sugar Beets, & Spinach, and Processing Study for Sugar Beets. MRID No. 42919701, -02, -03, and 42939701, -02. CBRS No. 12697 & 12830. DP Barcode: D195931 & D196714.

FROM: Leung Cheng, Chemist
Special Review Section II
Chemistry Branch II - Reregistration Support
Health Effects Division (7509C)

THROUGH: Andrew R. Rathman, Section Head
Chemistry Branch II - Reregistration Support
Health Effects Division (7509C)

TO: Kathryn Davis, CRM 52
Accelerated Reregistration Branch
Special Review/Reregistration Division (7508W)

Attached is a review of magnitude of residue studies on garden beets, sugar beets and spinach for cycloate submitted by the registrant for reregistration. This information was reviewed by Dynamac Corporation under the supervision of CBRS, HED. The data assessment has undergone secondary review in the branch and has been revised to reflect branch policies.

The registrant needs to submit frozen storage stability data for the three crop studies; these studies are underway. Also, the registrant needs to submit sugar beet residue data resulting from the application of the 10% G formulation and then propose tolerances for the combined residues of cycloate and its metabolites cis- and trans-3-hydroxycycloate, and cis- and trans-4-hydroxycycloate in/on sugar beet tops and roots to be consistent with the preharvest interval on the revised label.

The currently established tolerances, expressed as cycloate only, of 0.05 ppm in/on the roots and tops of garden beet are too low. The registrant must propose tolerances for the combined residues of cycloate and its metabolites cis- and trans-3-hydroxycycloate, and cis- and trans-4-hydroxycycloate in/on garden beet tops and roots at 1 and 0.5 ppm, respectively. The registrant should also revise their current label to propose a 65-day preharvest interval.

The registrant also must revise tolerances for the combined residues of cycloate and its metabolites cis- and trans-3-hydroxycycloate, and cis- and trans-4-hydroxycycloate in/on spinach upward to 0.5 ppm. They also need to revise their label to include a 65-day preharvest interval.

The submitted sugar beet processing is acceptable. The data indicate that the combined residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) concentrated 3.5x in molasses processed from sugar beet that received a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation at 2x. No concentration of residues was observed in pulp and sugar processed from similarly treated sugar beet roots. The registrant must propose a feed additive tolerance for the combined residues of cycloate and its metabolites cis- and trans-3-hydroxycycloate, and cis- and trans-4-hydroxycycloate in molasses when all the reregistration requirements for the sugar beet roots and adequate supporting storage stability data have been submitted.

If you need additional information, please advise.

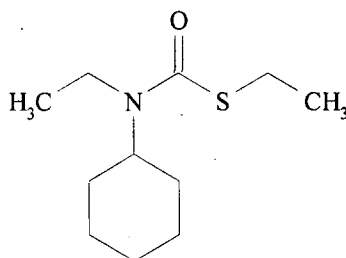
Attachment: Dynamac review of magnitude of residue studies

cc(with Attachment):Circ, RF, SF, List B File, Cheng, Dynamac

RDI:ARRathman:5/24/94:MMetzger:5/24/94:EZager:7/1/94

7509C:CBRS:LCheng:CM#2:RM8040D:5/23/94:7/1/94:03:a\CYCLOATE\MAGNRESI.DY
N

CYCLOATE



Shaughnessy No. 041301; Case
No. 2125

(CBRS No. 12697; DP Barcode D195931)

(CBRS No. 12830; DP Barcode D196714)

Task 4

REGISTRANT'S RESPONSE TO RESIDUE CHEMISTRY DATA REQUIREMENTS

BACKGROUND

The Cycloate Phase IV Reviews (S. Funk, 12/20/90) required field trial data depicting residues of cycloate and any regulated metabolites in/on the commodities of garden beets and spinach following application(s) of representative cycloate formulations in respective major crop-growing regions of the country according to the maximum registered use patterns. In addition, a sugar beet processing study was required to determine the potential for concentration of cycloate residues of concern in sugar beet processed fractions.

In response to the Cycloate Phase IV data requirements, Zeneca, Inc. (formerly ICI Americas, Inc.) has submitted data depicting the magnitude of the residues of cycloate, trans- and cis-3-hydroxycycloate (t-3HC and c-3HC), and trans- and cis-4-hydroxycycloate (t-4HC and c-4HC) in/on: (i) garden beets (1993; MRIDs 42919703 and 42939701); (ii) spinach (1993; MRID 42919702); and (iii) sugar beet processed commodities (1993; MRID 42939702). The registrant additionally submitted data from a new sugar beet field trial (1993; MRID 42919701). These studies are evaluated in this document for adequacy in fulfilling residue chemistry data requirements for the reregistration of cycloate. The Conclusions and Recommendations stated in this document pertain only to the topics listed above. Other data requirements stated in the Cycloate Phase IV Reviews are not addressed herein.

The qualitative nature of cycloate residues in plants is adequately understood (CBRS No. 9028, DP Barcode D171952, 5/19/92, C. Olinger) based on acceptable metabolism studies on sugar beets and spinach. The HED Metabolism Committee (see 5/18/92 memorandum of C. Olinger) has determined that the total toxic residues to be regulated include cycloate and the free and conjugated forms of its metabolites, 3-hydroxycycloate and 4-hydroxycycloate (stereoisomers included). The qualitative nature of cycloate residues in animals is not adequately understood. The requirements for poultry and ruminant metabolism studies remain outstanding.

Tolerances for residues of cycloate (S-ethyl cyclohexylethylthiocarbamate) in/on plant

commodities are presently expressed in terms of cycloate *per se* [40 CFR §180.212]. Tolerances for animal commodities and food/feed additives have not been established. A GLC method with steam distillation and/or acid hydrolysis and flame ionization detection, listed in PAM, Vol. II as Method A, is adequate for enforcement and collection of data on residues of cycloate *per se* in/on plant commodities. The Agency (CBRS No. 9028, DP Barcode D171952, 5/19/92, C. Olinger) has determined that new residue analytical method(s) capable of determining cycloate and all regulated metabolites in/on plants must be developed. The analytical method(s) must include a hydrolysis step which is capable of releasing conjugated residues of cis and trans isomers of 3-hydroxycycloate and 4-hydroxycycloate.

There are no established or proposed Codex MRLs for cycloate residues. Therefore, there are no issues of compatibility with respect to current U.S. tolerances and Codex MRLs.

CONCLUSIONS AND RECOMMENDATIONS

Magnitude of the Residue in Garden Beets

1. The submitted data from trials conducted in NY, OR, TX, and WI indicate that the combined residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) were <0.25 ppm (the combined LOQ for these analytes) in/on each of four samples of garden beet tops and roots harvested 65-93 days following a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation at 1x the maximum registered rate for each soil type. The additional data from a trial conducted in a CA sandy soil, following similar treatment at 1x, indicate that the combined residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) were <0.31 ppm in/on tops and <0.95 ppm in/on roots. These data are not presently supported by storage stability data. The registrant has indicated that a 3-year storage stability study on garden beet tops and roots was initiated in 1993. CBRS requires storage stability data for only 22 months since samples from the current submissions were stored frozen for a maximum of 22 months prior to residue analysis.
2. The currently established tolerances (expressed as cycloate *per se*) of 0.05 ppm in/on the roots and tops of garden beets are too low. The registrant must propose tolerances for the combined residues of cycloate and its metabolites to be regulated in/on garden beet tops and roots. The available data would support tolerance levels of 1 and 0.5 ppm in/on garden beet tops and roots, respectively. The registrant should also revise their current label to propose a 65-day preharvest interval.

Magnitude of the Residue in Sugar Beets

3. The submitted data indicate that the combined residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) were <0.25 ppm (the combined LOQ for these analytes) in/on each of eight samples of treated sugar beet tops and roots harvested 126-182 days following a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation at 1x the maximum registered rate. These data are not presently supported by storage stability data. The registrant has indicated that a 3-year storage stability study on sugar beet tops and roots was initiated in 1993. CBRS requires storage stability data for only 15 months since samples from the current submission were stored frozen for a maximum of 15 months prior to residue analysis.
4. The available data are incomplete to satisfy the reregistration requirements regarding this guideline topic because no field residue data are available reflecting the use of a

registered 10% granular (Roneet® 10-G, EPA Reg. No. 10182-177) formulation on sugar beets. According to EPA Guidance on Number and Location of Domestic Crop Field Trials issued 6/2/94 (E. Saito and E. Zager), granular formulations will generally require the full number of field trials regardless of what data are already available for other formulation classes. If the registrant wishes to support the G formulation, then the following additional data are required:

- Data depicting residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) in/on sugar beet tops and roots following a single pre-plant broadcast soil-incorporated application of the 10% G formulation 4 lb ai/A. A total of 12 field trials should be distributed among Region V (5), Region VII (1), Region VIII (1), Region IX (1), Region X (2) and Region XI (2). Two independently composited samples from each trial are required.
5. The registrant must propose tolerances for the combined residues of cycloate and its metabolites to be regulated in/on sugar beet tops and roots. The registrant also needs adequate storage stability data, field residue data for the G formulation and a label revision to include an appropriate PHI.

Magnitude of the Residue in Sugar Beet Processed Commodities

6. The submitted sugar beet processing study is acceptable. The data indicate that the combined residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) concentrated 3.5x in molasses processed from sugar beet roots that received a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation at 2x. No concentration of residues was observed in pulp and sugar processed from similarly treated sugar beet roots. These data are not presently supported by storage stability data. The registrant has indicated that a 3-year storage stability study on sugar beet processed commodities was initiated in 1993. CBRS requires storage stability data for only 8 months since processed sugar beet fractions from the current submission were stored frozen for a maximum of 8 months prior to residue analysis.
7. Based on a concentration factor of 3.5x, the registrant must propose a feed additive tolerance for the combined residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) in molasses when all the reregistration requirements for the RAC (sugar beet roots) and adequate supporting storage stability data have been submitted.

Magnitude of the Residue in Spinach

8. The submitted data indicate that the combined residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) ranged from <0.25 ppm (the combined LOQ for these analytes) to <0.31 ppm in/on each of five samples of spinach harvested 64-89 days following a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation at 1x the maximum registered rate. These data are not presently supported by storage stability data. The registrant has indicated that a 3-year storage stability study on spinach was initiated in 1993. CBRS requires storage stability data for only 18 months since samples from the current submission were stored frozen for a maximum of 18 months prior to residue analysis.
9. The currently established tolerance (expressed as cycloate *per se*) of 0.05 ppm in/on

spinach is too low. The registrant must propose tolerances for the combined residues of cycloate and its metabolites to be regulated in/on spinach. The available data would support a tolerance level of 0.5 ppm. The registrant should also revise their current label to propose a 65-day preharvest interval.

DETAILED CONSIDERATIONS

Residue Analytical Methods

In conjunction with the submitted field residue studies for garden beets (1993; MRIDs 42919703 and 42939701), spinach (1993; MRID 42919702), and sugar beets (1993; MRID 42919701), and sugar beet processing study (1993; MRID 42939702), Zeneca, Inc. submitted descriptions along with concurrent recovery data of a GC/NPD method (designated by the registrant as Tentative Residue Analytical Method, TRAM) for the determination of cycloate and its 3-hydroxy and 4-hydroxy metabolites.

Briefly, residues in/on plant commodities are extracted by blending with 50% aqueous acetone. After filtering, an aliquot of the extract is chilled on an ice bath, vacuum-evaporated to remove acetone, and then hydrolyzed by refluxing with 1 N HCl for two hours. The hydrolyzed residues are partitioned into dichloromethane, chilled, evaporated to remove dichloromethane, and mixed with toluene. Residues in the toluene fraction are derivatized with heptafluorobutyric anhydride (HFBA) at 60-65 C for 15-20 minutes. The derivatization procedure converts hydroxycycloate metabolites to HFBA esters; unconjugated cycloate *per se* does not react with HFBA. The toluene fraction is then washed with water, dried with anhydrous sodium sulfate, and analyzed by capillary GC/NPD. Metabolites are identified by comparison of retention times with the retention times of the following reference standards: cycloate, trans-3-hydroxycycloate, cis-3-hydroxycycloate, trans-4-hydroxycycloate, and cis-4-hydroxycycloate. The reported limit of quantitation for each analyte is 0.05 ppm. Confirmation of metabolites identified by GC/NPD is achieved by replacing the NPD with a mass selective detector (MSD) operating in the selective ion monitoring mode (SIM). The GC/MSD method also may be used to verify metabolite identities in the presence of co-extractive interfering substances in the samples.

The registrant provided concurrent method recoveries, which were included with each field trial and processing study data submission. Untreated control samples of garden beets, sugar beets and processed commodities, and spinach were separately fortified with cycloate, trans- and cis-3-hydroxycycloate, and trans- and cis-4-hydroxycycloate at 0.05 ppm. These method recovery data are presented in Table 1. Sample calculations and representative chromatograms were provided. The submitted method is adequate for collecting data on residues of cycloate, 3-hydroxycycloate, and 4-hydroxycycloate in/on garden beets, sugar beets and processed commodities, and spinach.

CBRS has concluded that the total toxic residues to be regulated include cycloate and the free and conjugated forms of its metabolites, cis- and trans-3-hydroxycycloate and cis- and trans-4-hydroxycycloate. Therefore, new residue analytical method(s) capable of determining cycloate and all regulated metabolites in/on plants must be developed for enforcement purposes. The analytical method must include a hydrolysis step which is capable of releasing conjugated residues of cis and trans isomers of 3-hydroxycycloate and 4-hydroxycycloate.

Table 1. Concurrent method recoveries of cycloate, 3-hydroxycycloate, and 4-hydroxycycloate from commodities of garden beets, sugar beets, and spinach (GC/NPD; Zeneca, Inc. TRAM).

Matrix	Forti- fication (ppm)	No. of Samples	Percent Recoveries ^a				
			Cycloate	t-3HC	c-3HC	t-4HC	c-4HC
Garden Beets (MRIDs 42919703 and 42039701)							
Roots	0.05	5	88-122	91-125	83-141	93-115	96-124
	0.10	1	102	129	134	124	124
Tops	0.05	3	91-130	101-116	101-130	97-123	112-121
	0.10	1	99	85	105	92	110
Sugar Beets (MRID 42919701)							
Roots	0.05	3	94-99	85-98	90-100	93, 99 ^b	76, 91 ^b
Tops	0.05	3	94-113	84-115	101-115	90-93	93-99
	2.00	1	110	113	116	109	111
Sugar Beet Processed Commodities (MRID 42939702)							
Roots	0.05	1	109	108	120	114	120
	0.50	1	104	111	122	112	120
Pulp	0.05	1	83	95	104	105	106
	0.50	1	102	101	108	105	111
Molasses	0.05	1	91	99	111	90	85
	0.50	1	107	120	115	109	116
Sugar	0.05	1	76	81	90	72	74
	0.50	1	76	88	87	73	92
Spinach (MRID 42919702)							
Spinach	0.05	3	94-117	86-131	88-135	86-117	87-122

^a All values are the highest of duplicate or triplicate analyses.

^b Two samples only.

Storage Stability Data

No new storage stability data were included to support the subject field trials and processing studies. The registrant indicated that 3-year storage stability studies were initiated in 1993 to validate the field trials for garden beets, sugar beets, and spinach as well as sugar beet processing commodities.

Magnitude of the Residue in Garden Beets

Tolerances of 0.05 ppm have been established for residues of cycloate *per se* in/on the roots and tops of garden beets [40 CFR §180.212].

A REFs search conducted 1/11/94 and a LUIS Report dated 10/25/90 identified one cycloate end-use product registered for use on garden beets. The 6 lb/gal EC (Roneet® 6-E, EPA Reg. No. 10182-178, 6/4/93) formulation is registered for a single pre-plant soil-incorporated broadcast or band application to garden beets grown on sandy soils at 3 lb ai/A or on heavy soils at 4 lb ai/A. Application is made in 20-50 gal of water/A using ground equipment.

Zeneca, Inc. submitted data (1993; MRIDs 42939701 and 42919703) from five tests conducted in CA(1), NY(1), OR(1), TX(1), and WI(1) depicting the combined residues of cycloate and its metabolites [trans- and cis-3-hydroxycycloate (t-3HC and c-3HC, respectively) and trans- and cis-4-hydroxycycloate (t-4HC and c-4HC, respectively)] in/on the commodities of garden beets. The roots and tops of garden beets were collected 65-93 days following a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation. The test formulation was applied at 3 lb ai/A in CA (sandy soil type) and at 4 lb ai/A in NY and OR (silt loam soil type), TX (sandy clay loam soil type), and WI (silty clay loam soil type). The applied rates are equivalent to 1x the maximum registered rate for each soil type. A minimum of 24 root samples and 12 top samples were harvested from each test location. All samples were frozen within four hours of harvest and shipped frozen to the Environmental Chemistry Section of Zeneca, Inc. (Richmond, CA) where they were stored frozen at -15 C prior to analysis. The total frozen storage interval from harvest to analysis was 459-665 days (~15-22 months).

Residues of cycloate and its metabolites were determined using the GC/NPD method previously described. The results of the field trials are presented in Table 2. Five control samples of garden beet tops and roots each bore apparent combined residues of <0.25 ppm (the combined LOQ for the analytes).

Geographic representation is adequate since the test states of CA(6%), NY(32%), OR(11%), TX(8%), and WI(30%) accounted for ~90% of the 1982 U.S. garden beet production (1982 *Census of Agriculture, Vol. 1, Part 51, p. 337*).

Table 2. Residues of cycloate and its metabolites of concern in/on the roots and tops of garden beets harvested 65-93 days following a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation at 1x.

State ^a	Rate (ai/A)	Uncorrected Residues (ppm) ^b					Total
		Cycloate	t-3HC	c-3HC	t-4HC	c-4HC	
Roots							
CA	3	<0.05	<0.05	0.11	<0.05	<0.05	<0.31
NY	4	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25
OR	4	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25
TX	4	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25
WI	4	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25
Tops							
CA	3	<0.05	0.44	0.30	0.11	<0.05	<0.95
NY	4	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25
OR	4	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25
TX	4	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25
WI	4	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25

^a Test site soils: CA, sandy; NY and OR, silt loam; TX, sandy clay loam, and WI, silty clay loam.

^b Values presented are the highest of duplicate analyses.

The submitted data from trials conducted in NY, OR, TX, and WI indicate that the combined residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) were <0.25 ppm (the combined LOQs for these analytes) in/on each of four samples of garden beet tops and roots harvested 65-93 days following a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation at 1x the maximum registered rate for each soil type. The additional data from a trial conducted in a CA sandy soil, following similar treatment at 1x, indicate that the combined residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) were <0.31 ppm in/on tops and <0.95 ppm in/on roots. These data are not presently supported by storage stability data. The registrant has indicated that a 3-year storage stability study on garden beet tops and roots was initiated in 1993. CBRS requires storage stability data for only 22 months since samples from the current submissions were stored frozen for a maximum of 22 months prior to residue analysis.

The currently established tolerances (expressed as cycloate *per se*) of 0.05 ppm in/on the roots and tops of garden beets are too low. Pending submission of acceptable storage stability data to validate the current residue trials, the registrant must propose tolerances for the combined residues of cycloate and its metabolites to be regulated in/on garden beet tops and roots. The available data would support tolerance levels of 1 and 0.5 ppm in/on garden beet tops and roots, respectively.

Magnitude of the Residue in Sugar Beets

Tolerances of 0.05 ppm have been established for residues of cycloate *per se* in/on the roots and tops of sugar beets [40 CFR §180.212].

A REFs search conducted 1/11/94 and a LUIS Report dated 10/25/90 identified two cycloate end-use product registered for use on sugar beets. The 10% G (Roneet® 10-G, EPA Reg. No. 10182-177, 9/23/85) and the 6 lb/gal EC (Roneet® 6-E, EPA Reg. No. 10182-178, 6/4/93)

formulations are registered for a single pre-plant soil-incorporated broadcast or band application to sugar beets grown on sandy soils at 3 lb ai/A or on heavy soils at 4 lb ai/A. The EC formulation is also registered for a single late fall application at 4 lb ai/A in ID, MN, MT, ND, OR, WY, and WA before the ground freezes, with the application to be made in 20-50 gal of water/A using ground equipment.

The Cycloate Phase IV Reviews (S. Funk, 12/20/90) concluded that acceptable data are available depicting the magnitude of residues of cycloate *per se* in/on sugar beet commodities following application of the EC formulation according to the maximum registered use patterns. No additional field residue data were required unless plant metabolism studies identify additional metabolites that need to be regulated. Plant metabolism has now been adequately delineated. The residues of concern are cycloate and the free and conjugated forms of its metabolites, 3-hydroxycycloate and 4-hydroxycycloate. Subsequently, a new sugar beet field residue study has been submitted by the registrant. These data are discussed below.

Zeneca, Inc. submitted data (1993; MRID 42919701) from eight tests conducted in CA(1), CO(1), ID(1), MI(1), MN(1), MT(1), NE(1), and ND(1) depicting the combined residues of cycloate and its metabolites [trans- and cis-3-hydroxycycloate (t-3HC and c-3HC, respectively) and trans- and cis-4-hydroxycycloate (t-4HC and c-4HC, respectively)] in/on the commodities of sugar beets. The roots and tops of sugar beets were harvested 126-182 days following a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation at 3.9-4.0 lb ai/A (1x the maximum registered rate) in 10-21 gal of water/A using ground equipment. The treated plots were planted with sugar beets on the same day of cycloate application. A minimum of 12 control and 12 treated plants were harvested from each test site at crop maturity. All samples were stored frozen within six hours of harvest and shipped frozen to the Environmental Chemistry Section of Zeneca, Inc. (Richmond, CA) where they were stored frozen at -15 C prior to analysis. The total frozen storage interval from harvest to analysis was 389-455 days (~13-15 months).

Residues of cycloate and its metabolites were determined using the GC/NPD method previously described. The combined uncorrected residues of cycloate, t-3HC, c-3HC, t-4HC, and c-4HC were <0.25 ppm (the combined LOQs for these analytes) in/on each of eight samples of treated sugar beet tops and roots. Eight control samples of sugar beet tops and roots each bore apparent combined residues <0.25 ppm.

Geographic representation is adequate since the test states of CA(13%), CO(3%), ID(18%), MI(9%), MN(22%), MT(5%), NE(6%), and ND(13%) accounted for ~90% of the 1991 U.S. sugar beet production (*Agricultural Statistics, 1991, USDA*).

The submitted data indicate that the combined residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) were <0.25 ppm (the combined LOQs for these analytes) in/on each of eight samples of treated sugar beet tops and roots harvested 126-182 days following a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation at 1x the maximum registered rate. These data are not presently supported by storage stability data. The registrant has indicated that a 3-year storage stability study on sugar beet tops and roots was initiated in 1993. CBRS requires storage stability data for only 15 months since samples from the current submission were stored frozen for a maximum of 15 months prior to residue analysis.

The available data are incomplete to satisfy the reregistration requirements regarding this guideline topic because no field residue data are available reflecting the use of a registered 10% granular (Roneet® 10-G, EPA Reg. No. 10182-177) formulation on sugar beets.

According to EPA Guidance on Number and Location of Domestic Crop Field Trials issued 6/2/94 (E. Saito and E. Zager), granular formulations will generally require the full number of field trials regardless of what data are already available for other formulation classes. If the registrant wishes to support the G formulation, then the following additional data are required:

- Data depicting residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) in/on sugar beet tops and roots following a single pre-plant broadcast soil-incorporated application of the 10% G formulation 4 lb ai/A. A total of 12 field trials should be distributed among Region V (5), Region VII (1), Region VIII (1), Region IX (1), Region X (2) and Region XI (2). Two independently composited samples from each trial are required.

Following submission of adequate storage stability data and field residue data reflecting use of a G formulation, the registrant must propose tolerances for the combined residues of cycloate and its metabolites to be regulated in/on sugar beet tops and roots.

Magnitude of the Residue in Sugar Beet Processed Commodities

No tolerances have been established for residues of cycloate in/on sugar beet processed commodities. See "Magnitude of the Residue in Sugar Beets" section for registered use patterns of cycloate.

Zeneca, Inc. submitted a sugar beet processing study (1993; MRID 42939702) conducted in CA. Sugar beets were harvested 196 days following a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation at 8 lb ai/A (2x the maximum registered rate) in 30 gal of water/A using ground equipment. [CBRS notes that the maximum theoretical concentration of sugar from the processing (based on separation into components) of sugar beets is 12.5x (see 1/93 memorandum on Maximum Theoretical Concentration Factors)]. At crop maturity, 300 lbs of sugar beets were separately harvested from the control and treated plots. Twelve root sub-samples were removed from each bulk sample and shipped frozen to the Environmental Chemistry Section of Zeneca, Inc. (Richmond, CA) for residue analysis. The remaining samples were shipped frozen to the processor (William J. Englar & Associates, Inc., Moses Lake, WA) where they were processed into pulp, sugar, and molasses. The registrant provided flow charts of the processing procedures which according to the registrant were representative of typical commercial practices; in addition data concerning the maximum theoretical concentration factor of sugar beet fractions, based on weight ratio of starting sugar beet roots to processed products, were provided. The processed fractions were shipped frozen to the analytical laboratory for residue analysis. The total frozen storage interval from harvest to analysis was 235-249 days (~8 months).

Residues of cycloate and its metabolites were determined using the GC/NPD method previously described. The results of the processing study are presented in Table 3. The apparent combined residues of cycloate and its metabolites were <0.25 ppm (the combined LOQs for the analytes) in/on each sample of untreated sugar beet roots, pulp, sugar, and molasses.

Table 3. Residues of cycloate and its metabolites of concern in/on the processed fractions of sugar beets treated with a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation at 2x.

Commodity	Uncorrected Residues (ppm) ^a					Concentration/Reduction factor	Theoretical Concentration Factor ^b
	Cycloate	t-3HC	c-3HC	t-4HC	c-4HC	Total	

Roots	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25	--	
Pulp	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25	--	27
Molasses	<0.05	0.19	0.38	0.17	0.08	<0.87	<3.5	117
Sugar	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25	--	81

^a Values are the highest of duplicate sample analyses.

^b Calculated by registrant based on weight ratio of starting sugar beet roots to processed products.

The submitted sugar beet processing study is acceptable. The data indicate that the combined residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) concentrated 3.5x in molasses processed from sugar beet roots that received a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation at 2x. No concentration of residues was observed in pulp and sugar processed from similarly treated sugar beet roots. These data are not presently supported by storage stability data. The registrant has indicated that a 3-year storage stability study on sugar beet processed commodity was initiated in 1993. CBRS requires storage stability data for only 8 months since processed sugar beet fractions from the current submission were stored frozen for a maximum of 8 months prior to residue analysis.

Based on a concentration factor of 3.5x, the registrant must propose a feed additive tolerance for the combined residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) in molasses when all the reregistration requirements for the RAC (sugar beet roots) and adequate supporting storage stability data have been submitted.

Magnitude of the Residue in Spinach

A tolerance of 0.05 ppm has been established for residues of cycloate *per se* in/on spinach [40 CFR §180.212].

A REFs search conducted 1/11/94 and a LUIS Report dated 10/25/90 identified one cycloate end-use product registered for use on spinach. The 6 lb/gal EC (Roneet® 6-E, EPA Reg. No. 10182-178, 6/4/93) formulation is registered for a single pre-plant soil-incorporated broadcast or band application to spinach grown in AR, CT, DE, MA, MD, ME, MS, NH, NJ, NY, OH, OK, PA, TX, VA, VT, and western TN at rates of 3 lb ai/A for sandy soils and 4 lb ai/A for heavy soils. Application is made in 20-50 gal of water/A using ground equipment.

Zeneca, Inc. submitted data (1993; MRID 42919702) from five tests conducted in AR(1), CA(2), MD(1), and TX(1) depicting the combined residues of cycloate and its metabolites [trans- and cis-3-hydroxycycloate (t-3HC and c-3HC, respectively) and trans- and cis-4-hydroxycycloate (t-4HC and c-4HC, respectively)] in/on spinach. Spinach were harvested 64-89 days following a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation. The test formulation was applied at 3 and 4 lb ai/A (0.75 and 1x the maximum registered rate, respectively) in CA; the test substance was applied at 4 lb ai/A (1x) in AZ, MD, and TX. A minimum of 12 control and 12 treated plants were harvested from each site at crop maturity. All samples were frozen or stored on dry/blue ice within four hours of harvest. Samples were shipped frozen to the Environmental Chemistry Section of Zeneca, Inc. (Richmond, CA) where they were stored at <-15 C prior to analysis. The total frozen storage interval from harvest to analysis was 387-547 days (~13-18 months).

Residues of cycloate and its metabolites were determined using the GC/NPD method previously described. The results of the field trials are presented in Table 4. Four control

samples of spinach each bore apparent combined residues < 0.25 ppm (the combined LOQs for the analytes).

Geographic representation is adequate since the test states of AR(4%), CA(25%), NJ(6%), and TX(25%) represent the major spinach-growing areas of the U.S. (*1982 Census of Agriculture, Vol. 1, Part 51, p. 352*).

Table 4. Residues of cycloate and its metabolites of concern in/on spinach harvested 64-89 days following a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation at 1x.

State	Rate (lb ai/A)	Uncorrected Residues (ppm) ^a					Total
		Cycloate	t-3HC	c-3HC	t-4HC	c-4HC	
AR	4	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25
CA	3	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25
CA	4	<0.05	<0.05	<0.05	<0.05	0.11	<0.31
NJ	4	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25
TX	4	<0.05	<0.05	<0.05	<0.05	<0.05	<0.25

^a Values presented are the highest of duplicate analyses.

The submitted data indicate that the combined residues of cycloate and its metabolites of concern (t-3HC, c-3HC, t-4HC and c-4HC) ranged from <0.25 ppm (the combined LOQs for these analytes) to <0.31 ppm in/on each of five samples of spinach harvested 64-89 days following a single pre-plant broadcast soil-incorporated application of the 6 lb/gal EC formulation at 1x the maximum registered rate. These data are not presently supported by storage stability data. The registrant has indicated that a 3-year storage stability study on spinach was initiated in 1993. CBRS requires storage stability data for only 18 months since samples from the current submissions were stored frozen for a maximum of 18 months prior to residue analysis.

The currently established tolerance (expressed as cycloate *per se*) of 0.05 ppm in/on spinach is too low. Pending submission of acceptable storage stability data to validate the current residue trials, the registrant must propose tolerances for the combined residues of cycloate and its metabolites to be regulated in/on spinach. The available data would support a tolerance level of 0.5 ppm.

EPA MEMORANDA CITED IN THIS DOCUMENT

CBRS No.: None
Subject: Cycloate Phase IV Reviews
From: S. Funk
To: A. Rathman and E. Zager
Dated: 12/20/90
MRID(s): None

CBRS No.: 9028
Subject: Reregistration Phase V: Cycloate Plant Metabolism Studies; Chemical No. 41301; Case No. 2125; DP Barcode D171952.
From: C.L. Olinger
To: E. Dobbins and L. Deluise
Dated: 5/19/92
MRID(s): 420903-01 and -02

MASTER RECORD IDENTIFICATION NUMBERS

Citations for the MRID documents referred to in this review are presented below.

42919701 Grant, C.L. and Herman, R. S. (1993) RO-NEET®: Magnitude of the Residue Study for Cycloate on Sugar Beets; Spring Application. Study Number CYCL-92-MR-03; Report Number RR 93-038B. Unpublished study prepared by ZENECA Ag Products, Richmond, CA. 203 p.

42919702 Grant, C.L. and Herman, R. S. (1993) RO-NEET®: Magnitude of the Residue Study for Cycloate on Spinach; Fall Planting. Study Number CYCL-91-MR-01; Report Number RR 93-036B. Unpublished study prepared by ZENECA Ag Products, Richmond, CA. 141 p.

42919703 Grant, C.L. and Herman, R. S. (1993) RO-NEET®: Magnitude of the Residue Study for Cycloate on Table Beets. Study Number CYCL-91-MR-02; Report Number RR 93-037B. Unpublished study prepared by ZENECA Ag Products, Richmond, CA. 150 p.

42939701 Grant, C.L. and Herman, R. S. (1993) RO-NEET®: Magnitude of the Residue Study for Cycloate on Table Beets. Study Number CYCL-92-MR-01; Report Number RR 93-063B. Unpublished study prepared by ZENECA Ag Products, Richmond, CA. 98 p.

42939702 Grant, C.L. and Herman, R. S. (1993) RO-NEET®: Residue Processing Study for Cycloate on Sugar Beets. Study Number CYCL-92-PR-01; Report Number RR 93-059B. Unpublished study prepared by ZENECA Ag Products, Richmond, CA. 92 p.

F
041306 73.5

24(c) CHECKLIST

STATE: <u>OREGON</u>	SLN No <u>OR 0100, 23</u>
DATE REGISTERED: <u>06/27/01</u>	90-DAY DATE: _____
SPECIFIC SPECIAL LOCAL NEED: _____	SITE: _____
_____	PEST/PROBLEM: _____

-
1. Is the State certified to issue this type of registration? _____
 2. Was the EPA Application/Notification Form submitted? _____
 3. Was all the required information included on the form? _____
 4. Was a confidential formula submitted (for new products)? _____
 5. Is this registration for a "CHANGED USE PATTERN"? _____
 6. Has an FR document been prepared for this "CHANGED USE PATTERN"? _____

Federal Register publication date: _____

7. Tolerances required? _____ Established? _____ Citation: _____
8. Full labeling being used? _____ Supplemental directions? _____
9. Does label state "FOR DISTRIBUTION AND USE ONLY WITHIN (State)"? _____
10. Does full label comply with 40 CFR 162.10, as follows:

- a. Product name, brand or trademark? _____
- b. Name and address of registrant? _____
- c. Net contents? _____
- d. Product registration number? _____
- e. Producing establishment number? _____
- f. Ingredient statement? _____
- g. Precautionary labeling? _____
- h. Directions for use for special local need? _____
- i. Use classification? _____

Was proper format followed? _____

11. Is supplemental directions for use labeling satisfactory? _____
12. Was supplemental labeling compared with EPA-registered label? _____

COMMENTS: _____

1. SLN No. OR 0160 23 2. PM 25 3. Action Code _____

4. State Issue Date

0	6	2	7	0	1
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5. Date received by EPA

0	7	0	9	0	
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6. Date received by PM

--	--	--	--	--	--

7. Chemical name _____

8. Chemical code _____

9. Use _____

10. Reviews requested:

	Date Sent	Due Date	Date Returned	Response Code	Response Date
HED					
EFB					
RCB					
EEB					
TB					
RD					
PM					
S					
Precaut. Labeling					
Chemistry					
Efficacy					

11. Status _____

12. FINAL ACTION" Response code _____

Response date

--	--	--	--	--	--



United States Environmental Protection Agency
Office of Pesticide Programs, Registration Division (7505C)
Washington, DC 20460

**Application for/Notification of State Registration
of a Pesticide To Meet a Special Local Need**
(Pursuant to section 24(c) of the Federal Insecticide,
Fungicide, and Rodenticide Act, as Amended)

For State Use Only
Registration No. Assigned
OR-010023
Date Registration Issued
June 27, 2001
EXPIRES
December 31, 2004

1. Name and Address of Applicant for Registration TRI AG, INC. 5100 Poplar Avenue, Suite 2414 Memphis, Tennessee 38137		2. Product is (Check one) <input checked="" type="checkbox"/> EPA-Registered <input type="checkbox"/> New (not EPA-registered) <input type="checkbox"/> Attach EPA Form 8570-4, Confidential Statement of Formula for new products.		EPA Registration Number 73637-5
		3. Active Ingredient(s) in Product cycloate		EPA Company Number 73637
4. Product Name RO-NEET 6-E		5. If this is a food/feed use, a tolerance or other residue clearance is required. Cite appropriate regulations in 40 CFR Part 180, 185, and/or 186. 180.212 <u>PC# = 041301</u>		
6. Type of Registration (Give details in Item 13 or on a separate page, properly identified and attached to this form): <input type="checkbox"/> a. To permit use of a new product. <input checked="" type="checkbox"/> b. To amend EPA registrations for one or more of the following purposes: <input type="checkbox"/> (1) To permit use on additional crops or animals. <input checked="" type="checkbox"/> (2) To permit use at additional sites. <input type="checkbox"/> (3) To permit use against additional pests. <input type="checkbox"/> (4) To permit use of additional application techniques or equipment. <input type="checkbox"/> (5) To permit use at different application rates. <input type="checkbox"/> (6) Other (specify below)		7. Nature of Special Local Need (check one) <input type="checkbox"/> There is no pesticide product registered by EPA for such use. <input checked="" type="checkbox"/> There is no EPA-registered pesticide product which, under the conditions of use within the State, would be as safe and/or as efficacious for such use within the terms and conditions of EPA registration. <input type="checkbox"/> An appropriate EPA-registered pesticide product is not available.		
10. Has FIFRA section 24(c) registration for this use of the product ever, by another State, been (check appropriate box(es), if known): <input checked="" type="checkbox"/> Sought <input checked="" type="checkbox"/> Issued <input type="checkbox"/> Denied <input type="checkbox"/> Revoked If any of the above are checked, list States in Item 13 below. <input type="checkbox"/> No FIFRA section 24(c) Action		8. If this registration is an amendment to an EPA-registered product, is it for a "new use" as defined in 40 CFR 152.3? <input type="checkbox"/> Yes (discuss in Item 13 below) <input checked="" type="checkbox"/> No 9. Has an EPA Registration or Experimental Use Permit for this chemical ever been (check applicable box(es), if known): <input checked="" type="checkbox"/> Sought <input checked="" type="checkbox"/> Issued <input type="checkbox"/> Denied <input type="checkbox"/> Cancelled <input type="checkbox"/> Suspended <input checked="" type="checkbox"/> Registration <input type="checkbox"/> Experimental Use Permit <input type="checkbox"/> No Previous Permit Action		
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		11. Endangered Species Act: (Give details in Item 13 or on a separate page, properly identified and attached to this form) Identify the counties where this pesticide will be used. If Statewide, indicate "all." Provide a list of Federally protected endangered/threatened species which occur in the areas of proposed use.		
Signature of Applicant or Authorized Representative 		12. Indicate use status of Special Local Need, i.e., planned dates of use: From: <u>3/1/01</u> To: <u>8/31/01</u>		
Title Director of Regulatory Affairs		13. Comments (attach additional sheet, if needed) This SLN was originally issued to Zeneca and transferred to TRI AG 12/1/00. No substitute herbicides after ANTOR was withdrawn for use on spinach. The 24(c) to be controlled by Chiquita Processed Foods under an indemnification agreement (attached). Application pending in state of Washington.		
Telephone Number (901) 260-5423		Date <u>3/13/01</u>		

Determination by State Agency

This registration is for a Special Local Need and is being issued in accordance with section 24(c) of FIFRA, as amended. To the best of our knowledge, the information above is correct, except as noted in "Comments" below or in attachments.

Name, Title, and Address of State Agency Official Roseann Kachadourian Registration Specialist - ODA 635 Capitol St NE Salem OR 97301		Comments (by State Agency Only)	Received by EPA
Title 			
Telephone Number (503) 986-4651	Date <u>6-27-01</u>		

DR. Paul
07/11/61

PRODUCT INFORMATION

TRI AG, INC.

REGISTRATION FOR SPECIAL LOCAL NEED
FOR DISTRIBUTION AND USE ONLY WITHIN THE STATE OF OREGON

RO-NEET® 6-E

EPA Reg. No. 73637-5

EPA SLN No. OR-010023

This label valid until December 31, 2004 or until otherwise amended, withdrawn, canceled, or suspended.

FOR USE ON SPINACH

ACTIVE INGREDIENT:

S-ethyl cyclohexylethylthiocarbamate 73.9%

INERT INGREDIENTS: 26.1%

TOTAL 100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT

FIRST AID: If a known exposure occurs or is suspected, immediately start the recommended procedures below. Simultaneously contact a Poison Control Center, a physician, or the nearest hospital. Describe the situation and follow the advice given.

IF SWALLOWED: Immediately give large quantities of water but DO NOT induce vomiting. *This product contains hydrocarbon solvent.* If vomiting does occur, give fluids again. Have a physician determine if condition of patient will permit evacuation of stomach. DO NOT give anything by mouth to an unconscious person. Call a physician immediately.

IF IN EYES: Hold eyelids apart and flush eyes with large amounts of running water for 15 minutes. Get medical attention if irritation occurs.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED: Remove to fresh air. Get medical attention if respiratory irritation occurs.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

HARMFUL IF SWALLOWED. Avoid contact with skin, eyes, and clothing. Avoid contamination of feed or food.

Personal Protective Equipment (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category E on an EPA chemical resistance category selection chart.

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical-resistant gloves, such as barrier laminate or nitrile rubber or neoprene rubber or viton
- Shoes plus socks

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

NEW
JUN 27 2001

ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry to treated areas during the restricted-entry interval (REI) of 12 hours. Exception: If the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

PPE required for early entry into treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

- Coveralls
- Chemical-resistant gloves, such as barrier laminate or nitrile rubber or neoprene rubber or viton
- Shoes plus socks

SPINACH: Apply a surface broadcast application with ground application equipment prior to planting. Apply 0.34 to 0.50 gallons RO-NEET 6-E (2-3 lbs. ai) per acre on sandy mineral soils only in a minimum of 20 gallons of water. Immediately (within minutes) after application thoroughly mix RO-NEET 6-E into the soil to a depth of 2 to 3 inches using a finishing disk, harrow, rolling cultivator or similar implement capable of providing uniform incorporation.

WEEDS CONTROLLED: For List of Weeds Controlled See EPA-registered RO-NEET 6-E Label.

Do not apply this product through any type of irrigation system.

Special Conditions and Disclaimer for use of RO-NEET on Spinach.

TRI AG, INC. intends that this Section 24(c) label be distributed only to end users and/or growers (and/or applicators acting on behalf of growers) who agree to the terms and conditions below, and agree in writing to the terms and conditions required including a waiver and release from all liability and indemnification by the user and/or grower of TRI AG, INC. and others for failure to perform and crop damage from the use of RO-NEET 6-E on spinach grown for canning. If such terms and conditions are unacceptable, return RO-NEET 6-E at once unopened.

This product when used on spinach grown for canning may lead to crop injury, loss, or damage. TRI AG, INC. recommends that the user and/or grower test this product in order to determine its suitability for such intended use. TRI AG, INC. makes this product available to the user and/or grower solely to the extent the benefit and utility, in the sole opinion of the user and/or grower, outweigh, the extent of potential injury associated with the use of this product. The decision to use or not to use this product must be made by each individual user and/or grower on the basis of possible crop

injury from RO-NEET 6-E, the severity of weed infestation, the cost of alternative weed controls, and other factors. Because of the risk of failure to perform or crop damage, all such use is at the user's and/or grower's risk.

This labeling must be in the possession of the user at the time of pesticide application.

Follow all applicable directions, restrictions and precautions on the EPA-registered label.

IMPORTANT: Read the entire Directions for Use and the Conditions of Sale and Warranty before using this product.

**CONDITIONS OF SALE
AND LIMITATION OF WARRANTY AND LIABILITY**

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product should be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of TRI AG or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold TRI AG and Seller harmless for any claims relating to such factors.

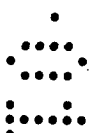
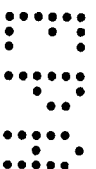
TRI AG warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or TRI AG, and Buyer and User assume the risk of any such use. TRI AG MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

In no event shall TRI AG or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF TRI AG AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF TRI AG OR SELLER, THE REPLACEMENT OF THE PRODUCT.

TRI AG and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sale and limitations of warranty and of liability, which may not be modified except by written agreement signed by a duly authorized representative of TRI AG.

RO-NEET 6-E is a trademark of Cedar Chemical Corp.
24(c) Registrant: TRI AG

EPA SLN NO: OR-010023



PRODUCT INFORMATION

CEDAR CHEMICAL CORP.



**REGISTRATION FOR SPECIAL LOCAL NEED
FOR DISTRIBUTION AND USE ONLY WITHIN THE STATE OF OREGON**

RO-NEET® 6-E

EPA Reg. No. 73637-5-56077

EPA SLN No. OR-010023

This label valid until December 31, 2004 or until otherwise amended, withdrawn, canceled, or suspended.

FOR USE IN SPINACH

ACTIVE INGREDIENT:

S-ethyl cyclohexylethylthiocarbamate 73.9%

INERT INGREDIENTS: 26.1%

TOTAL 100.0%

NEW
JUN 27 2001

KEEP OUT OF REACH OF CHILDREN

CAUTION

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IF IN EYES: Hold eyelids apart and flush eyes with large amounts of running water for 15 minutes. Get medical attention if irritation occurs.

IF ON SKIN: Wash with plenty of soap and water. Get medical attention if irritation persists.

IF INHALED: Remove to fresh air. Get medical attention if respiratory irritation occurs.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

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Personal Protective Equipment (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category E on an EPA chemical resistance category selection chart.

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical-resistant gloves, such as barrier laminate or nitrile rubber or neoprene rubber or viton
- Shoes plus socks

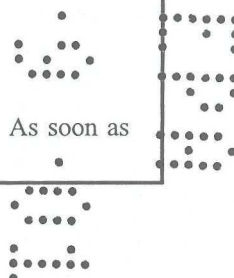
Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

When handlers use closed systems, enclosed cabs, or aircraft in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240(d)(4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.



ENVIRONMENTAL HAZARDS

Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR part 170. This Standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval (REI). The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry to treated areas during the restricted-entry interval (REI) of 12 hours. Exception: If the product is soil-injected or soil-incorporated, the Worker Protection Standard, under certain circumstances, allows workers to enter the treated area if there will be no contact with anything that has been treated.

PPE required for early entry into treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water, is:

- Coveralls
- Chemical-resistant gloves, such as barrier laminate or nitrile rubber or neoprene rubber or viton
- Shoes plus socks

SPINACH: Apply a surface broadcast application with ground application equipment prior to planting. Apply 0.34 to 0.50 gallons RO-NEET 6-E (2-3 lbs. ai) per acre on sandy mineral soils only in a minimum of 20 gallons of water. Immediately (within minutes) after application thoroughly mix RO-NEET 6-E into the soil to a depth of 2 to 3 inches using a finishing disk, harrow, rolling cultivator or similar implement capable of providing uniform incorporation.

WEEDS CONTROLLED: For List of Weeds Controlled See EPA-registered RO-NEET 6-E Label.

Do not apply this product through any type of irrigation system.

Special Conditions and Disclaimer for use of RO-NEET on Spinach.

Cedar intends that this Section 24(c) label be distributed only to end users and/or growers (and/or applicators acting on behalf of growers) who agree to the terms and conditions below, and agree in writing to the terms and conditions required including a waiver and release from all liability and indemnification by the user and/or grower of Cedar and others for failure to perform and crop damage from the use of RO-NEET 6-E on spinach grown for canning. If such terms and conditions are unacceptable, return RO-NEET 6-E at once unopened.

This product when used on spinach grown for canning may lead to crop injury, loss, or damage. Cedar recommends that the user and/or grower test this product in order to determine its suitability for such intended use. Cedar makes this product available to the user and/or grower solely to the extent the benefit and utility, in the sole opinion of the user and/or grower, outweigh, the extent of potential injury associated with the use of this product. The decision to use or not to use this product must be made by each individual user and/or grower on the basis of possible crop injury from RO-NEET 6-E, the severity of weed infestation, the cost of alternative weed controls, and other factors. Because of the risk of failure to perform or crop damage, all such use is at the user's and/or grower's risk.

This labeling must be in the possession of the user at the time of pesticide application.

Follow all applicable directions, restrictions and precautions on the EPA-registered label.

IMPORTANT: Read the entire Directions for Use and the Conditions of Sale and Warranty before using this product.

**CONDITIONS OF SALE
AND LIMITATION OF WARRANTY AND LIABILITY**

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product should be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions, presence of other materials or other influencing factors in the use of the product, which are beyond the control of Cedar or Seller. All such risks shall be assumed by Buyer and User, and Buyer and User agree to hold Cedar and Seller harmless for any claims relating to such factors.

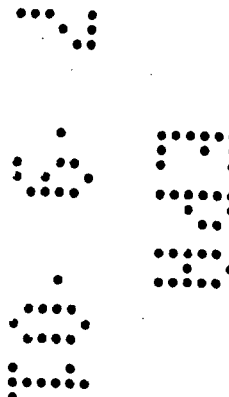
Cedar warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. This warranty does not extend to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to or beyond the control of Seller or Cedar, and Buyer and User assume the risk of any such use. Cedar **MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.**

In no event shall Cedar or Seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF Cedar AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF Cedar OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

Cedar and Seller offer this product, and Buyer and User accept it, subject to the foregoing conditions of sale and limitations of warranty and of liability, which may not be modified except by written agreement signed by a duly authorized representative of Cedar.

RO-NEET 6-E is a trademark of Cedar Chemical Corp.
24(c) Registrant: TRI AG, INC.

EPA SLN NO: OR-010023





Oregon

John A. Kitzhaber, M.D., Governor

Department of Agriculture

635 Capitol Street NE
Salem, OR 97301-2532

June 27, 2001

Document Processing Desk (SLN)
Office of Pesticide Programs - 7504C
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Ave. NW
Washington, D.C. 20460-0001



RE: TRI AG, INC./ RO-NEET 6-E (a.i. cycloate)
EPA Reg. No. 73637-5 EPA SLN No. OR-010023
Site- Spinach
Expiration Date - December 31, 2004

In 1994, the Oregon Department of Agriculture (ODA) issued SLN No. OR-940026 for the use of Zeneca/RO-NEET 6-E on spinach in Umatilla County. EPA SLN No. OR-940026 will be canceled by Syngenta when all Zeneca/RO-NEET has cleared the channels of trade.

TRI AG, INC. is currently the registrant of RO-NEET 6-E. Enclosed is a registration under Section 24(c) for the use of TRI AG, INC./RO-NEET 6-E on spinach, EPA SLN No. OR-010023. EPA SLN No. OR-010023 is identical to EPA SLN No. OR-940026, except that OR-010023 is not limited to Umatilla county, meets current format requirements and has an expiration date. In addition, there is a disclaimer for use on page 2 of the label.

It should be noted that the Section 3 has uses on spinach, but is restricted to certain states (Oregon is excluded). It is my understanding that TRI AG, INC. will be discussing with EPA plans to incorporate this Oregon use, onto the Section 3 label. At that time the SLN will be canceled.

In addition, as a matter of courtesy, I have enclosed a copy of the distributor SLN label, Cedar Chemical Corporation/RO-NEET 6-E, EPA SLN No. OR-010023. Please note, it is acknowledged that TRI AG, INC. is the Section 24(c) registrant. When TRI AG, INC. selects to cancel the RO-NEET SLN registration (OR-010023), the Cedar Chemical label will automatically become invalid.

If you have any questions, please do not hesitate to contact me. Thank you.

Sincerely,

Rose Kachadoorian
Registration Specialist
Pesticides Division, Oregon Department of Agriculture
503/986-4651 Phone, 503/986-4735 Fax
Email Address: rkachado@oda.state.or.us

CC: PICOL
Tom Darnell, OSU Ext
Lynn Jensen, OSU Ext
Jeanie Betsher, Cedar Chemical
John Kieft, Syngenta* Western Research Center
* Formerly Zeneca Ag. Products



July 11, 2001

Oregon Department of Agriculture
Pesticides Division
635 Capitol Street, NE
Salem, OR 97301

ATTN: RoseAnn Kachadoorian, Specialist

SUBJECT: Receipt of New 24 (c)

Dear State Agency:

The Office of Pesticide Programs acknowledges receipt of the 24(c) application/notification for OR010023. The package is being forwarded to the Product Manager for review.

To ensure that the Agency receives proper notification of your 24(c) applications/notifications it is necessary to use the correct mailing address. All new 24(c) applications should be sent to the following:

Document Processing Desk (SLN)
Office of Pesticide Programs - H7504C
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue
Washington, DC 20004

If you have any questions concerning the administrative screening of the package please contact the Front End Unit at (703) 305-5780.

Sincerely,

Front End Processing Staff
Information Services Branch
Program Management and Support Division



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES